OIPE IAP38 JUN 05 2006 PATENT & TRADEMARK OFFICE

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Marc ALIZON et al.	Group Art Unit: 1637
Application No.: 08/308,219	Examiner: Jeffrey Norman Fredman
Filed: September 19, 1994	Confirmation No.: 4832

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) (as amended)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REQUEST TO CORRECT INVENTORSHIP

Pursuant to 37 C.F.R. § 1.48, applicants request that the inventorship in this application be corrected as follows.

Pursuant to 37 C.F.R. § 1.48 (c), please add the following inventors to this application:

Robert C. Gallo,
Milkulas Popovic,
Mangalasseril G. Sarngadharan,
Solange Chamaret,
Claudine Axler-Bin,
Francoise Rey,
Marie-Therese Nugeyre,
Jacqueline Gruest,
Charles Dauget,
Willy Rozenbaum,
Christine Rouzioux,
Francoise Brun-Vezinet,
Luc Montagnier,
Jean-Claude Chermann,

Francoise Barre-Sinoussi, and
Pierre Tiollais.

The addition of the above-named inventors is necessitated by amendment of the claims during prosecution of this application.

A statement from each person being added as an inventor that the addition is necessitated by amendment of the claims and that the inventorship error occurred without deceptive intent is enclosed.

A Declaration by each of the actual inventors is enclosed. One copy of the application is enclosed although each Declaration was attached to a copy of the application when it was executed. The duplicate copies of the application have been removed to reduce the size of the submission, but will be provided by applicants if the Examiner requires them.

The written consent of each of the assignees is enclosed.

A check for the required fee of $130.00 under § 1.17(c) is enclosed.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: June 5, 2006

By: _____

Salvatore J. Arrigo
Registration No. 46,063
Telephone: 202-408-4160
Facsimile: 202-408-4400
E-mail: arrigos@finnegan.com

DECLARATION

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; I believe I am an original, first, and joint inventor of the subject matter of claims 25, 29, and 32, which is claimed and for which a patent is sought on the invention entitled: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) the specification of which was filed on September 19, 1994, as United States Application No. 08/308,219 and Confirmation No. 4832.

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FRANCE	84 16013	October 18, 1984	☒ YES ☐ NO
UNITED KINGDOM	84 23659	September 19, 1984	☒ YES ☐ NO
UNITED KINGDOM	83 24800	September 15, 1983	☒ YES ☐ NO

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Full Name of First Inventor: Robert C. Gallo	Inventor's Signature Robert C. Gallo	Date May 31, '06
Residence 9100 Aldershot Drive, Bethesda, Maryland 20817-1902		Citizenship United States
Post Office Address 9100 Aldershot Drive, Bethesda, Maryland 20817-1902		
Full Name of Second Inventor Mikulas Popovic	Inventor's Signature	Date
Residence 9917 Holmhurst Road, Bethesda, Maryland 20817		Citizenship United States
Post Office Address 9917 Holmhurst Road, Bethesda, Maryland 20817		
Full Name of Third Inventor: Mangalasseril G. Sarngadharan	Inventor's Signature	Date
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Full Name of Seventh Inventor: Marie-Therese Nugeyre	Inventor's Signature	Date
Residence 92130 Issy-les-Moulineaux, France		Citizenship French
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Full Name of Eighth Inventor Jacqueline Gruest (Deceased) Jacques Gruest (Legal Successor)	Inventor's Signature	Date
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Full Name of Thirteenth Inventor: Luc Montagnier	Inventor's Signature	Date
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Full Name of Twenty-First Inventor: Oliver Danos	Inventor's Signature	Date
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Residence 9100 Aldershot Drive, Bethesda, Maryland 20817-1902		Citizenship United States
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Full Name of Third Inventor: Mangalasseril G. Samgadharan	Inventor's Signature	Date
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Full Name of Fourth Inventor: Solange Chamaret	Inventor's Signature S Chamaret	Date 24-05-06
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UNITED KINGDOM	84 23659	September 19, 1984	☒ YES ☐ NO
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Full Name of Thirteenth Inventor: Luc Montagnier	Inventor's Signature	Date
Residence 21 rue de Malabry, 92350 Le Plessis-Robinson, France		Citizenship French
Post Office Address 21 rue de Malabry, 92350 Le Plessis-Robinson, France		
Full Name of Fourteenth Inventor Jean-Claude Chermann	Inventor's Signature	Date
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Post Office Address Le Messuguet, 22 rue Cardalino, 13260 Cassis, France		
Full Name of Fifteenth Inventor: Francoise Barre-Sinoussi	Inventor's Signature	Date
Residence 104 de Capricorne, 50 rue d'Érevan, 92130 Issy les Moulineaux, Franch		Citizenship French
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Full Name of Ninteenth Inventor: Simon Wain-Hobson	Inventor's Signature	Date
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Full Name of Twentieth Inventor Stewart Cole	Inventor's Signature	Date
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Post Office Address 23 bis rue Cécile Dunant, 92140 Clahart, France		
Full Name of Twenty-First Inventor: Oliver Danos	Inventor's Signature	Date
Residence 173 rue Saint Merry, 7730 Fontainebleau, France		Citizenship French
Post Office Address 173 rue Saint Merry, 7730 Fontainebleau, France		

DECLARATION

I, JACQUELINE GRUEST, as the heir of JACQUELINE GRUEST, who is deceased, do hereby make the following declaration on her behalf:

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; I believe I am an original, first, and joint inventor of the subject matter, which is claimed and for which a patent is sought on the invention entitled: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) the specification of which was filed on September 19, 1994, as United States Application No. 08/308,219 and Confirmation No. 4832.

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UNITED KINGDOM	84 23659	September 19, 1984	☒ YES ☐ NO
UNITED KINGDOM	83 24800	September 15, 1983	☒ YES ☐ NO

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Full Name of Third Inventor: Mangalasseril G. Samgadharan	Inventor's Signature	Date
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Full Name of Seventh Inventor: Marie-Therese Nugeyre	Inventor's Signature	Date
Residence 92130 Issy-les-Moulineaux, France		Citizenship French
Post Office Address 92130 Issy-les-Moulineaux, France		

Full Name of Eighth Inventor Jacqueline Gruest (Deceased) Jacques Gruest (Legal Successor)	Inventor's Signature	Date 25.05.2006
Residence Grue du Gué, 94240 L'Hay les Roses, France		Citizenship French
Post Office Address Grue du Gué, 94240 L'Hay les Roses, France		

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Full Name of Sixth Inventor Francoise Rey	Inventor's Signature	Date
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Full Name of Eighth Inventor Jacqueline Gruest (Deceased) Jacques Gruest (Legal Successor)	Inventor's Signature	Date
Residence Grue du Gué, 94240 L'Hay les Roses, France		Citizenship French
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Full Name of Ninth Inventor: Charles Dauguet	Inventor's Signature Charles Dauguet	Date 26 Mai 2006
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Full Name of Tenth Inventor Willy Rozenbaum	Inventor's Signature	Date
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Residence 9100 Aldershot Drive, Bethesda, Maryland 20817-1902		Citizenship United States
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Customer Number 22,852
Attorney Docket No. 3495.0010-20

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Full Name of Thirteenth Inventor: Luc Montagnier	Inventor's Signature	Date
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Post Office Address 21 rue de Malabry, 92350 Le Plessis-Robinson, France		
Full Name of Fourteenth Inventor Jean-Claude Chermann	Inventor's Signature Jean Claude Chermann	Date May 26. 06
Residence Le Messuguet, 22 rue Cardalino, 13260 Cassis, France		Citizenship French
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Full Name of Twenty-First Inventor: Oliver Danos	Inventor's Signature	Date
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Residence 9100 Aldershot Drive, Bethesda, Maryland 20817-1902		Citizenship United States
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Full Name of Second Inventor Mikulas Popovic	Inventor's Signature	Date
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Full Name of Third Inventor: Mangalasseril G. Samgadharan	Inventor's Signature	Date
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Application Data Sheet
U.S. Application No. 08/308,219
Filed: September 19, 1994
Attorney Docket No. 03495.0010-20000

Application Information

Application No.::	08/308/219
Filing Date::	09/18/1994
Title Line One::	DNA Sequence of the LTR Region of Human
Title Line Two::	Immunodeficiency Virus Type 1 (HIV-1) (as amended)
Total Drawing Sheets::	26
Formal Drawings?::	N/A
Application Type::	Utility
Docket Number::	03495.0010-20000

Representative Information

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Domestic Priority Information

Application:	Continuity Type:	Parent Application:	Parent Filing Date:
This application	Division of	07/158,652	02/22/88
07/158,652	Division of	06/771,248	08/30/85
This application	Continuation-in-part of	07/999,410	12/31/92
07/999,410	Continuation of	07/499,210	03/19/90
07/499,210	Continuation of	06/771,230	08/30/95
06/771,230	Continuation-in-part of	06/706,562	02/28/85
06/706,562	Continuation-in-part of	06/558,109	12/05/83

Foreign Priority Information

Country:	Application Number:	Filing Date:	Priority Claimed:
United Kingdom	84 29099	11/16/84	Yes
France	84 16013	10/18/84	Yes
United Kingdom	83 24800	09/15/83	Yes
United Kingdom	84 23659	09/19/84	Yes

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Citizenship Country:: United States

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc Alizon et al.

Application No.: 08/308,219

Filed: September 19,1994

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Group Art Unit: 1637

Examiner: Jeffrey N. Fredman

Confirmation No.: 4832

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

POWER OF ATTORNEY

Applicants' Assignee hereby grants power of attorney to **FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P. Customer Number 22,852,** to transact all business in the Patent and Trademark Office connected therewith, and to receive the Letters Patent. Please also send all future correspondence concerning this application to Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., Customer Number 22,852

The undersigned is authorized to sign this Power of Attorney.

Respectfully submitted,

Dated: JUNE 6, 2006

By: Jack Spiegel
Name: JACK SPIEGEL (REG # 34,477)
Title: SENIOR ADVISOR FOR TECHNOLOGY TRANSFER OPERATIONS
Assignee: United States of America as represented by the Secretary of the Department of Health and Human Services

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT OF CHRISTINE ROUZIOUX
(Being Added As An Inventor)

I have read U.S. application Serial No. 08/308,219.

I am informed that I was not named as an inventor in application Serial No. 08/308,219 when the application was filed in the U.S. Patent and Trademark Office.

I have been informed that the claims in U.S. application Serial No. 08/308,219 have been amended by adding claims 17-22, 25, and 27-40 to the application.

I am informed that a copy of claims 17-22, 25, and 27-40 is attached hereto.

I have read claims 17-22, 25, and 27-40, which I am informed were added to U.S. application Serial No. 08/308,219 to claim previously unclaimed subject matter.

I understand that I am being added as an inventor to U.S. application Serial No. 08/308,219.

I have been informed that my addition as an inventor to U.S. application Serial No. 08/308,219 is necessitated by the amendment of the claims by adding claims 17-22, 25, and 27-40 to the application.

The inventorship error resulting from the amendment of the claims by adding claims 17-22, 25, and 27-40 to U.S. application Serial No. 08/308,219 occurred without deceptive intention on my part.

I hereby declare that all statements made of my own knowledge and belief are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Christine Rovzar

By: _____

Date: 30.05.2006

U.S. Patent Application No. 08/308,219
Filed: September 19, 1994
Inventors: Marc ALIZON et al.
Div. of 07/158,652 (02/22/88);
Div. of 06/771,248 (08/30/85);
CIP of 07/999,410 (12/31/92);
Cont. of 07/499,210 (03/19/90);
Cont of 06/771,230 (08/30/85);
CIP of 06/706,562 (02/28/85)'
CIP of 06/558,109 (12/5/83)
DI No.: 84-37
Our Reference: 03495.0010-20000

Pending Claims

17. A purified recombinant DNA of human immunodeficiency virus type 1 (HIV-1), wherein the DNA comprises the sequence:

8570	8580	8590	8600	8610
GGGGGACTGG	AAGGGCTAAT	TCACTCCCAA	CGAAGACAAG	ATATCCTTGA
8620	8630	8640	8650	8660
TCTGTGGATC	TACCACACAC	AAGGCTACTT	CCCTGATTGG	CAGAACTACA
8670	8680	8690	8700	8710
CACCAGGGCC	AGGGGTCAGA	TATCCACTGA	CCTTTGGATG	GTGCTACAAG
8720	8730	8740	8750	8760
CTAGTACCAG	TTGAGCCAGA	TAAGGTAGAA	GAGGCCAATA	AAGGAGAGAA
8770	8780	8790	8800	8810
CACCAGCTTG	TTACACCCTG	TGAGCCTGCA	TGGAATGGAT	GACCCTGAGA
8820	8830	8840	8850	8860
GAGAAGTGTT	AGAGTGGAGG	TTTGACAGCC	GCCTAGCATT	TCATCACGTG
8870	8880	8890	8900	8910
GCCCGAGAGC	TGCATCCGGA	GTACTTCAAG	AACTGCTGAC	ATCGAGCTTG
8920	8930	8940	8950	8960
CTACAAGGGA	CTTTCCGCTG	GGGACTTTCC	AGGGAGGCGT	GGCCTGGGCG
8970	8980	8990	9000	9010
GAACTGGGGA	GTGGCGAGCC	CTCAGATGCT	GCATATAAGC	AGCTGCTTTT

```
      9020        9030        9040        9050        9060
TGCCTGTACT  GGGTCTCTCT  GGTTAGACCA  GATTTGAGCC TGGGAGCTCT

      9070        9080        9090     9097           10
CTGGCTAACT  AGGGAACCCA  CTGCTTAAGC  CTCAATA     AAGCTTGCCT

        20          30          40          50          60
TGAGTGCTTC  AAGTAGTGTG  TGCCCGTCTG  TTGTGTGACT  CTGGTAACTA
        70          80          90         100         110
GAGATCCCTC  AGACCCTTTT  AGTCAGTGTG  GAAAATCTCT  AGCAGTGGCG

       120         130         140         150       159
CCCGAACAGG  GACTTGAAAG  CGAAAGGGAA  ACCAGAGGAG CTCTCTCGA
```

18. The purified recombinant DNA of claim 17, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

19. A method of using the purified recombinant DNA of claim 17 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

20. The method of claim 19, wherein the biological fluid is blood.

21. A method of using the purified recombinant DNA of claim 18 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

22. The method of claim 21, wherein the biological fluid is blood.

25. A method for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA.

27. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

28. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

29. A method for preparing HIV-1 RNA for detecting the presence of

HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA.

30. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

31. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

32. A method for preparing HIV-1 RNA for detecting the presence of

HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) isolating HIV-1 virions from the cell-free supernatant; and

(c) disrupting the virions to release HIV-1 RNA.

33. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

34. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

35. A purified fragment of the recombinant DNA of claim 17, wherein said fragment comprises the sequence: CTCAATAAAGCTTGCCTTG.

36. The purified fragment of claim 35, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

37. A method of using the purified fragment of claim 35 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 35 and detecting hybridization between the HIV-1 RNA and the purified fragment.

38. The method of claim 37, wherein the biological fluid is blood.

39. A method of using the purified fragment of claim 36 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 36 and detecting hybridization between the HIV-1 RNA and the purified fragment.

40. The method of claim 39, wherein the biological fluid is blood.

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc Alizon et al.

Application No.: 08/308,219

Filed: September 19,1994

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Group Art Unit: 1637

Examiner: Jeffrey N. Fredman

Confirmation No.: 4832

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Sir:

STATEMENT OF LUC MONTAGNIER
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I have read U.S. application Serial No. 08/308,219.

I am informed that I was not named as an inventor in application Serial No. 08/308,219 when the application was filed in the U.S. Patent and Trademark Office.

I have been informed that the claims in U.S. application Serial No. 08/308,219 have been amended by adding claims 17-22, 25, and 27-40 to the application.

I am informed that a copy of claims 17-22, 25, and 27-40 is attached hereto.

I have read claims 17-22, 25, and 27-40, which I am informed were added to U.S. application Serial No. 08/308,219 to claim previously unclaimed subject matter.

I understand that I am being added as an inventor to U.S. application Serial No. 08/308,219.

I have been informed that my addition as an inventor to U.S. application Serial No. 08/308,219 is necessitated by the amendment of the claims by adding claims 17-22, 25, and 27-40 to the application.

The inventorship error resulting from the amendment of the claims by adding claims 17-22, 25, and 27-40 to U.S. application Serial No. 08/308,219 occurred without deceptive intention on my part.

I hereby declare that all statements made of my own knowledge and belief are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: _____

Date: May 24 2006

U.S. Patent Application No. 08/308,219
Filed: September 19, 1994
Inventors: Marc ALIZON et al.
Div. of 07/158,652 (02/22/88);
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CIP of 07/999,410 (12/31/92);
Cont. of 07/499,210 (03/19/90);
Cont of 06/771,230 (08/30/85);
CIP of 06/706,562 (02/28/85)'
CIP of 06/558,109 (12/5/83)
DI No.: 84-37
Our Reference: 03495.0010-20000

Pending Claims

17. A purified recombinant DNA of human immunodeficiency virus type 1 (HIV-1), wherein the DNA comprises the sequence:

8570	8580	8590	8600	8610
GGGGGACTGG	AAGGGCTAAT	TCACTCCCAA	CGAAGACAAG	ATATCCTTGA
8620	8630	8640	8650	8660
TCTGTGGATC	TACCACACAC	AAGGCTACTT	CCCTGATTGG	CAGAACTACA
8670	8680	8690	8700	8710
CACCAGGGCC	AGGGGTCAGA	TATCCACTGA	CCTTTGGATG	GTGCTACAAG
8720	8730	8740	8750	8760
CTAGTACCAG	TTGAGCCAGA	TAAGGTAGAA	GAGGCCAATA	AAGGAGAGAA
8770	8780	8790	8800	8810
CACCAGCTTG	TTACACCCTG	TGAGCCTGCA	TGGAATGGAT	GACCCTGAGA
8820	8830	8840	8850	8860
GAGAAGTGTT	AGAGTGGAGG	TTTGACAGCC	GCCTAGCATT	TCATCACGTG
8870	8880	8890	8900	8910
GCCCGAGAGC	TGCATCCGGA	GTACTTCAAG	AACTGCTGAC	ATCGAGCTTG
8920	8930	8940	8950	8960
CTACAAGGGA	CTTTCCGCTG	GGGACTTTCC	AGGGAGGCGT	GGCCTGGGCG
8970	8980	8990	9000	9010
GAACTGGGGA	GTGGCGAGCC	CTCAGATGCT	GCATATAAGC	AGCTGCTTTT

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      9020        9030        9040        9050        9060
TGCCTGTACT  GGGTCTCTCT  GGTTAGACCA  GATTTGAGCC  TGGGAGCTCT

      9070        9080        9090        9097          10
CTGGCTAACT  AGGGAACCCA  CTGCTTAAGC  CTCAATA       AAGCTTGCCT

        20          30          40          50          60
TGAGTGCTTC  AAGTAGTGTG  TGCCCGTCTG  TTGTGTGACT  CTGGTAACTA
        70          80          90         100         110
GAGATCCCTC  AGACCCTTTT  AGTCAGTGTG  GAAAATCTCT  AGCAGTGGCG

       120         130         140         150         159
CCCGAACAGG  GACTTGAAAG  CGAAAGGGAA  ACCAGAGGAG  CTCTCTCGA
```

18. The purified recombinant DNA of claim 17, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

19. A method of using the purified recombinant DNA of claim 17 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

20. The method of claim 19, wherein the biological fluid is blood.

21. A method of using the purified recombinant DNA of claim 18 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

22. The method of claim 21, wherein the biological fluid is blood.

25. A method for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA.

27. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

28. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

29. A method for preparing HIV-1 RNA for detecting the presence of
HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA.

30. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

31. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

32. A method for preparing HIV-1 RNA for detecting the presence of
HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) isolating HIV-1 virions from the cell-free supernatant; and

(c) disrupting the virions to release HIV-1 RNA.

33. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

34. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

35. A purified fragment of the recombinant DNA of claim 17, wherein said fragment comprises the sequence: CTCAATAAAGCTTGCCTTG.

36. The purified fragment of claim 35, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

37. A method of using the purified fragment of claim 35 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 35 and detecting hybridization between the HIV-1 RNA and the purified fragment.

38. The method of claim 37, wherein the biological fluid is blood.

39. A method of using the purified fragment of claim 36 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 36 and detecting hybridization between the HIV-1 RNA and the purified fragment.

40. The method of claim 39, wherein the biological fluid is blood.

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc Alizon et al.

Application No.: 08/308,219

Filed: September 19,1994

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Group Art Unit: 1637

Examiner: Jeffrey N. Fredman

Confirmation No.: 4832

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT OF JEAN-CLAUDE CHERMANN
(Being Added As An Inventor)

I have read U.S. application Serial No. 08/308,219.

I am informed that I was not named as an inventor in application Serial No. 08/308,219 when the application was filed in the U.S. Patent and Trademark Office.

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I hereby declare that all statements made of my own knowledge and belief are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: Jean-Claude Chermann

Date: May 26, 06

U.S. Patent Application No. 08/308,219
Filed: September 19, 1994
Inventors: Marc ALIZON et al.
Div. of 07/158,652 (02/22/88);
Div. of 06/771,248 (08/30/85);
CIP of 07/999,410 (12/31/92);
Cont. of 07/499,210 (03/19/90);
Cont of 06/771,230 (08/30/85);
CIP of 06/706,562 (02/28/85)'
CIP of 06/558,109 (12/5/83)
DI No.: 84-37
Our Reference: 03495.0010-20000

Pending Claims

17. A purified recombinant DNA of human immunodeficiency virus type 1 (HIV-1), wherein the DNA comprises the sequence:

8570	8580	8590	8600	8610
GGGGGACTGG	AAGGGCTAAT	TCACTCCCAA	CGAAGACAAG	ATATCCTTGA
8620	8630	8640	8650	8660
TCTGTGGATC	TACCACACAC	AAGGCTACTT	CCCTGATTGG	CAGAACTACA
8670	8680	8690	8700	8710
CACCAGGGCC	AGGGGTCAGA	TATCCACTGA	CCTTTGGATG	GTGCTACAAG
8720	8730	8740	8750	8760
CTAGTACCAG	TTGAGCCAGA	TAAGGTAGAA	GAGGCCAATA	AAGGAGAGAA
8770	8780	8790	8800	8810
CACCAGCTTG	TTACACCCTG	TGAGCCTGCA	TGGAATGGAT	GACCCTGAGA
8820	8830	8840	8850	8860
GAGAAGTGTT	AGAGTGGAGG	TTTGACAGCC	GCCTAGCATT	TCATCACGTG
8870	8880	8890	8900	8910
GCCCGAGAGC	TGCATCCGGA	GTACTTCAAG	AACTGCTGAC	ATCGAGCTTG
8920	8930	8940	8950	8960
CTACAAGGGA	CTTTCCGCTG	GGGACTTTCC	AGGGAGGCGT	GGCCTGGGCG
8970	8980	8990	9000	9010
GAACTGGGGA	GTGGCGAGCC	CTCAGATGCT	GCATATAAGC	AGCTGCTTTT

9020	9030	9040	9050	9060
TGCCTGTACT	GGGTCTCTCT	GGTTAGACCA	GATTTGAGCC	TGGGAGCTCT
9070	9080	9090	9097	10
CTGGCTAACT	AGGGAACCCA	CTGCTTAAGC	CTCAATA	AAGCTTGCCT
20	30	40	50	60
TGAGTGCTTC	AAGTAGTGTG	TGCCCGTCTG	TTGTGTGACT	CTGGTAACTA
70	80	90	100	110
GAGATCCCTC	AGACCCTTTT	AGTCAGTGTG	GAAAATCTCT	AGCAGTGGCG
120	130	140	150	159
CCCGAACAGG	GACTTGAAAG	CGAAAGGGAA	ACCAGAGGAG	CTCTCTCGA

18. The purified recombinant DNA of claim 17, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

19. A method of using the purified recombinant DNA of claim 17 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

20. The method of claim 19, wherein the biological fluid is blood.

21. A method of using the purified recombinant DNA of claim 18 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

22. The method of claim 21, wherein the biological fluid is blood.

25. A method for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA.

27. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

28. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

29. A method for preparing HIV-1 RNA for detecting the presence of

HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA.

30. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

31. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

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(b) isolating HIV-1 virions from the cell-free supernatant; and

(c) disrupting the virions to release HIV-1 RNA.

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35. A purified fragment of the recombinant DNA of claim 17, wherein said fragment comprises the sequence: CTCAATAAAGCTTGCCTTG.

36. The purified fragment of claim 35, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

37. A method of using the purified fragment of claim 35 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 35 and detecting hybridization between the HIV-1 RNA and the purified fragment.

38. The method of claim 37, wherein the biological fluid is blood.

39. A method of using the purified fragment of claim 36 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 36 and detecting hybridization between the HIV-1 RNA and the purified fragment.

40. The method of claim 39, wherein the biological fluid is blood.

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc Alizon et al.

Application No.: 08/308,219

Filed: September 19,1994

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Group Art Unit: 1637

Examiner: Jeffrey N. Fredman

Confirmation No.: 4832

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT OF FRANÇOISE BARRE-SINOUSS
(Being Added As An Inventor)

I have read U.S. application Serial No. 08/308,219.

I am informed that I was not named as an inventor in application Serial No. 08/308,219 when the application was filed in the U.S. Patent and Trademark Office.

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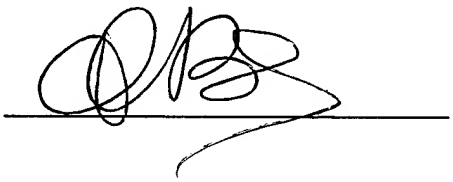
By: 

Date: 05.24.2006

U.S. Patent Application No. 08/308,219
Filed: September 19, 1994
Inventors: Marc ALIZON et al.
Div. of 07/158,652 (02/22/88);
Div. of 06/771,248 (08/30/85);
CIP of 07/999,410 (12/31/92);
Cont. of 07/499,210 (03/19/90);
Cont of 06/771,230 (08/30/85);
CIP of 06/706,562 (02/28/85)'
CIP of 06/558,109 (12/5/83)
DI No.: 84-37
Our Reference: 03495.0010-20000

Pending Claims

17. A purified recombinant DNA of human immunodeficiency virus type 1 (HIV-1), wherein the DNA comprises the sequence:

8570	8580	8590	8600	8610
GGGGGACTGG	AAGGGCTAAT	TCACTCCCAA	CGAAGACAAG	ATATCCTTGA
8620	8630	8640	8650	8660
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8670	8680	8690	8700	8710
CACCAGGGCC	AGGGGTCAGA	TATCCACTGA	CCTTTGGATG	GTGCTACAAG
8720	8730	8740	8750	8760
CTAGTACCAG	TTGAGCCAGA	TAAGGTAGAA	GAGGCCAATA	AAGGAGAGAA
8770	8780	8790	8800	8810
CACCAGCTTG	TTACACCCTG	TGAGCCTGCA	TGGAATGGAT	GACCCTGAGA
8820	8830	8840	8850	8860
GAGAAGTGTT	AGAGTGGAGG	TTTGACAGCC	GCCTAGCATT	TCATCACGTG
8870	8880	8890	8900	8910
GCCCGAGAGC	TGCATCCGGA	GTACTTCAAG	AACTGCTGAC	ATCGAGCTTG
8920	8930	8940	8950	8960
CTACAAGGGA	CTTTCCGCTG	GGGACTTTCC	AGGGAGGCGT	GGCCTGGGCG
8970	8980	8990	9000	9010
GAACTGGGGA	GTGGCGAGCC	CTCAGATGCT	GCATATAAGC	AGCTGCTTTT

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      9020        9030        9040        9050        9060
TGCCTGTACT  GGGTCTCTCT  GGTTAGACCA  GATTTGAGCC TGGGAGCTCT

      9070        9080        9090     9097            10
CTGGCTAACT  AGGGAACCCA  CTGCTTAAGC  CTCAATA     AAGCTTGCCT

        20          30          40          50          60
TGAGTGCTTC  AAGTAGTGTG  TGCCCGTCTG  TTGTGTGACT  CTGGTAACTA
        70          80          90         100         110
GAGATCCCTC  AGACCCTTTT  AGTCAGTGTG  GAAAATCTCT  AGCAGTGGCG

       120         130         140         150       159
CCCGAACAGG  GACTTGAAAG  CGAAAGGGAA  ACCAGAGGAG CTCTCTCGA
```

18. The purified recombinant DNA of claim 17, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

19. A method of using the purified recombinant DNA of claim 17 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

20. The method of claim 19, wherein the biological fluid is blood.

28. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

29. A method for preparing HIV-1 RNA for detecting the presence of

HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA.

30. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

31. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

32. A method for preparing HIV-1 RNA for detecting the presence of

HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

21. A method of using the purified recombinant DNA of claim 18 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

22. The method of claim 21, wherein the biological fluid is blood.

25. A method for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA.

27. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

(b) isolating HIV-1 virions from the cell-free supernatant; and

(c) disrupting the virions to release HIV-1 RNA.

33. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

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35. A purified fragment of the recombinant DNA of claim 17, wherein said fragment comprises the sequence: CTCAATAAAGCTTGCCTTG.

36. The purified fragment of claim 35, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

37. A method of using the purified fragment of claim 35 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

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(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 35 and detecting hybridization between the HIV-1 RNA and the purified fragment.

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39. A method of using the purified fragment of claim 36 for detecting the presence of HIV-1 RNA comprising:

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Customer No. 22,852
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc Alizon et al.

Application No.: 08/308,219

Filed: September 19,1994

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Group Art Unit: 1637

Examiner: Jeffrey N. Fredman

Confirmation No.: 4832

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT OF PIERRE TIOLLAIS
(Being Added As An Inventor)

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By: _____

Date: 24 mai 06

U.S. Patent Application No. 08/308,219
Filed: September 19, 1994
Inventors: Marc ALIZON et al.
Div. of 07/158,652 (02/22/88);
Div. of 06/771,248 (08/30/85);
CIP of 07/999,410 (12/31/92);
Cont. of 07/499,210 (03/19/90);
Cont of 06/771,230 (08/30/85);
CIP of 06/706,562 (02/28/85)'
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8770	8780	8790	8800	8810
CACCAGCTTG	TTACACCCTG	TGAGCCTGCA	TGGAATGGAT	GACCCTGAGA
8820	8830	8840	8850	8860
GAGAAGTGTT	AGAGTGGAGG	TTTGACAGCC	GCCTAGCATT	TCATCACGTG
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GCCCGAGAGC	TGCATCCGGA	GTACTTCAAG	AACTGCTGAC	ATCGAGCTTG
8920	8930	8940	8950	8960
CTACAAGGGA	CTTTCCGCTG	GGGACTTTCC	AGGGAGGCGT	GGCCTGGGCG
8970	8980	8990	9000	9010
GAACTGGGGA	GTGGCGAGCC	CTCAGATGCT	GCATATAAGC	AGCTGCTTTT

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      9020        9030        9040        9050        9060
TGCCTGTACT  GGGTCTCTCT  GGTTAGACCA  GATTTGAGCC TGGGAGCTCT

      9070        9080        9090     9097           10
CTGGCTAACT  AGGGAACCCA  CTGCTTAAGC  CTCAATA     AAGCTTGCCT

        20          30          40          50          60
TGAGTGCTTC  AAGTAGTGTG  TGCCCGTCTG  TTGTGTGACT  CTGGTAACTA
        70          80          90         100         110
GAGATCCCTC  AGACCCTTTT  AGTCAGTGTG  GAAAATCTCT  AGCAGTGGCG

       120         130         140         150         159
CCCGAACAGG  GACTTGAAAG  CGAAAGGGAA  ACCAGAGGAG CTCTCTCGA
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34. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

35. A purified fragment of the recombinant DNA of claim 17, wherein said fragment comprises the sequence: CTCAATAAAGCTTGCCTTG.

36. The purified fragment of claim 35, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

37. A method of using the purified fragment of claim 35 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 35 and detecting hybridization between the HIV-1 RNA and the purified fragment.

38. The method of claim 37, wherein the biological fluid is blood.

39. A method of using the purified fragment of claim 36 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 36 and detecting hybridization between the HIV-1 RNA and the purified fragment.

40. The method of claim 39, wherein the biological fluid is blood.

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc Alizon et al.

Application No.: 08/308,219

Filed: September 19,1994

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Group Art Unit: 1637

Examiner: Jeffrey N. Fredman

Confirmation No.: 4832

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT OF ROBERT C. GALLO
(Being Added As An Inventor)

I have read U.S. application Serial No. 08/308,219.

I am informed that I was not named as an inventor in application Serial No. 08/308,219 when the application was filed in the U.S. Patent and Trademark Office.

I have been informed that the claims in U.S. application Serial No. 08/308,219 have been amended by adding claims 25, 29, and 32 to the application.

I am informed that a copy of claims 25, 29, and 32 is attached hereto.

I have read claims 25, 29, and 32, which I am informed were added to U.S. application Serial No. 08/308,219 to claim previously unclaimed subject matter.

I understand that I am being added as an inventor to U.S. application Serial No. 08/308,219.

I have been informed that my addition as an inventor to U.S. application Serial No. 08/308,219 is necessitated by the amendment of the claims by adding 25, 29, and 32 to the application.

The inventorship error resulting from the amendment of the claims by adding claims 25, 29, and 32 to U.S. application Serial No. 08/308,219 occurred without deceptive intention on my part.

I hereby declare that all statements made of my own knowledge and belief are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: Robert C. Gallo

Date: May 31, 06

25. A method for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA.

29. A method for preparing HIV-1 RNA for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA.

32. A method for preparing HIV-1 RNA for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) isolating HIV-1 virions from the cell-free supernatant; and

(c) disrupting the virions to release HIV-1 RNA.

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc Alizon et al.

Application No.: 08/308,219

Filed: September 19,1994

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Group Art Unit: 1637

Examiner: Jeffrey N. Fredman

Confirmation No.: 4832

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT OF MIKULAS POPOVIC
(Being Added As An Inventor)

I have read U.S. application Serial No. 08/308,219.

I am informed that I was not named as an inventor in application Serial No. 08/308,219 when the application was filed in the U.S. Patent and Trademark Office.

I have been informed that the claims in U.S. application Serial No. 08/308,219 have been amended by adding claims 25, 29, and 32 to the application.

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I have read claims 25, 29, and 32, which I am informed were added to U.S. application Serial No. 08/308,219 to claim previously unclaimed subject matter.

I understand that I am being added as an inventor to U.S. application Serial No. 08/308,219.

I have been informed that my addition as an inventor to U.S. application Serial No. 08/308,219 is necessitated by the amendment of the claims by adding 25, 29, and 32 to the application.

The inventorship error resulting from the amendment of the claims by adding claims 25, 29, and 32 to U.S. application Serial No. 08/308,219 occurred without deceptive intention on my part.

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By: Mikulas Tajori

Date: June 1, 2006

25. A method for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA.

29. A method for preparing HIV-1 RNA for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA.

32. A method for preparing HIV-1 RNA for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) isolating HIV-1 virions from the cell-free supernatant; and

(c) disrupting the virions to release HIV-1 RNA.

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc Alizon et al.

Application No.: 08/308,219

Filed: September 19,1994

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Group Art Unit: 1637

Examiner: Jeffrey N. Fredman

Confirmation No.: 4832

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT OF MANGALASSERIL G. SARNGADHARAN
(Being Added As An Inventor)

I have read U.S. application Serial No. 08/308,219.

I am informed that I was not named as an inventor in application Serial No. 08/308,219 when the application was filed in the U.S. Patent and Trademark Office.

I have been informed that the claims in U.S. application Serial No. 08/308,219 have been amended by adding claims 25, 29, and 32 to the application.

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I understand that I am being added as an inventor to U.S. application Serial No. 08/308,219.

I have been informed that my addition as an inventor to U.S. application Serial No. 08/308,219 is necessitated by the amendment of the claims by adding 25, 29, and 32 to the application.

The inventorship error resulting from the amendment of the claims by adding claims 25, 29, and 32 to U.S. application Serial No. 08/308,219 occurred without deceptive intention on my part.

I hereby declare that all statements made of my own knowledge and belief are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: Mangalasseril G. Samgadharan

Date: June 4, 2006

25. A method for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA.

29. A method for preparing HIV-1 RNA for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA.

32. A method for preparing HIV-1 RNA for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) isolating HIV-1 virions from the cell-free supernatant; and

(c) disrupting the virions to release HIV-1 RNA.

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc Alizon et al.

Application No.: 08/308,219

Filed: September 19,1994

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Group Art Unit: 1637

Examiner: Jeffrey N. Fredman

Confirmation No.: 4832

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

CONSENT OF ASSIGNEE THE UNITED STATES OF AMERICA TO AMENDMENT OF INVENTORSHIP

The United States of America as represented by the Secretary of the Department of Heath and Human Services, having its principal place of business at 900 Rockville Pike, Bethesda, Maryland 20892, as an Assignee of the above-identified application, does hereby consent to amendment of inventorship from the inventive entity:

Marc Alizon
Pierre Sonigo
Simon Wain-Hobson
Stewart Cole
Oliver Danos

to the inventive entity:

Robert C. Gallo
Mikulas Popovic
Mangalasseril G. Sarngadharan
Solange Chamaret
Claudine Axler-Blin
Françoise Rey
Marie-Therese Nugeyre
Jacqueline Gruest
Charles Dauguet
Willy Rozenbaum
Christine Rouzioux
François Brun-Vezinet
Luc Montagnier
Jean-Claude Chermann
Françoise Barre-Sinoussi
Pierre Tiollais
Marc Alizon
Pierre Sonigo
Simon Wain-Hobson
Stewart Cole
Oliver Danos

The undersigned is authorized to act on behalf of the Assignee, the United States of America as represented by the Secretary of the Department of Heath and Human Services.

I hereby declare that all statements made of my own knowledge and belief are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

By: Jack Spiegel
Name: JACK SPIEGEL (REG# 34,477)
Title: SENIOR ADVISOR FOR TECHNOLOGY TRANSFER OPERATIONS
For Assignee: The United States of America
as represented by the
Secretary of the Department of
Health and Human Services.

Dated: JUNE 5, 2006

1110249

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Marc Alizon et al.	Group Art Unit: 1637
Application No.: 08/308,219	Examiner: Jeffrey N. Fredman
Filed: September 19,1994	Confirmation No.: 4832

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

CONSENT OF ASSIGNEE INSTITUT PASTEUR
TO AMENDMENT OF INVENTORSHIP

Institut Pasteur, duly organized under the laws of France and having its principal place of business at 28, rue du Docteur Roux, 75724 Paris Cedex 15, France, as an Assignee of the above-identified application, does hereby consent to amendment of inventorship from the inventive entity:

Marc Alizon
Pierre Sonigo
Simon Wain-Hobson
Stewart Cole
Oliver Danos

to the inventive entity:

Solange Chamaret
Claudine Axler-Blin
Françoise Rey
Marie-Therese Nugeyre
Jacqueline Gruest
Charles Dauguet
Willy Rozenbaum
Christine Rouzioux
François Brun-Vezinet
Luc Montagnier
Jean-Claude Chermann
Françoise Barre-Sinoussi
Pierre Tiollais
Marc Alizon
Pierre Sonigo
Simon Wain-Hobson
Stewart Cole
Oliver Danos
Robert C. Gallo
Mikulas Popovic
Mangalasseril G. Sarngadharan

The undersigned is authorized to act on behalf of the Assignee, Institut Pasteur.

I hereby declare that all statements made of my own knowledge and belief are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

A. Dautry

By: _____
Name: Alice Dautry
Title: President
For Assignee: Institut Pasteur

Dated: _____ June 1st, 2006

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Marc Alizon et al.	Group Art Unit: 1637
Application No.: 08/308,219	Examiner: Jeffrey N. Fredman
Filed: September 19,1994	Confirmation No.: 4832

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT OF SOLANGE CHAMARET
(Being Added As An Inventor)

I have read U.S. application Serial No. 08/308,219.

I am informed that I was not named as an inventor in application Serial No. 08/308,219 when the application was filed in the U.S. Patent and Trademark Office.

I have been informed that the claims in U.S. application Serial No. 08/308,219 have been amended by adding claims 17-22, 25, and 27-40 to the application.

I am informed that a copy of claims 17-22, 25, and 27-40 is attached hereto.

I have read claims 17-22, 25, and 27-40, which I am informed were added to U.S. application Serial No. 08/308,219 to claim previously unclaimed subject matter.

I understand that I am being added as an inventor to U.S. application Serial No. 08/308,219.

I have been informed that my addition as an inventor to U.S. application Serial No. 08/308,219 is necessitated by the amendment of the claims by adding claims 17-22, 25, and 27-40 to the application.

The inventorship error resulting from the amendment of the claims by adding claims 17-22, 25, and 27-40 to U.S. application Serial No. 08/308,219 occurred without deceptive intention on my part.

I hereby declare that all statements made of my own knowledge and belief are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: S Uamaru V

Date: 24-05-2006

U.S. Patent Application No. 08/308,219
Filed: September 19, 1994
Inventors: Marc ALIZON et al.
Div. of 07/158,652 (02/22/88);
Div. of 06/771,248 (08/30/85);
CIP of 07/999,410 (12/31/92);
Cont. of 07/499,210 (03/19/90);
Cont of 06/771,230 (08/30/85);
CIP of 06/706,562 (02/28/85)'
CIP of 06/558,109 (12/5/83)
DI No.: 84-37
Our Reference: 03495.0010-20000

Pending Claims

17. A purified recombinant DNA of human immunodeficiency virus type 1 (HIV-1), wherein the DNA comprises the sequence:

8570	8580	8590	8600	8610
GGGGGACTGG	AAGGGCTAAT	TCACTCCCAA	CGAAGACAAG	ATATCCTTGA
8620	8630	8640	8650	8660
TCTGTGGATC	TACCACACAC	AAGGCTACTT	CCCTGATTGG	CAGAACTACA
8670	8680	8690	8700	8710
CACCAGGGCC	AGGGGTCAGA	TATCCACTGA	CCTTTGGATG	GTGCTACAAG
8720	8730	8740	8750	8760
CTAGTACCAG	TTGAGCCAGA	TAAGGTAGAA	GAGGCCAATA	AAGGAGAGAA
8770	8780	8790	8800	8810
CACCAGCTTG	TTACACCCTG	TGAGCCTGCA	TGGAATGGAT	GACCCTGAGA
8820	8830	8840	8850	8860
GAGAAGTGTT	AGAGTGGAGG	TTTGACAGCC	GCCTAGCATT	TCATCACGTG
8870	8880	8890	8900	8910
GCCCGAGAGC	TGCATCCGGA	GTACTTCAAG	AACTGCTGAC	ATCGAGCTTG
8920	8930	8940	8950	8960
CTACAAGGGA	CTTTCCGCTG	GGGACTTTCC	AGGGAGGCGT	GGCCTGGGCG
8970	8980	8990	9000	9010
GAACTGGGGA	GTGGCGAGCC	CTCAGATGCT	GCATATAAGC	AGCTGCTTTT

9020	9030	9040	9050	9060
TGCCTGTACT	GGGTCTCTCT	GGTTAGACCA	GATTTGAGCC	TGGGAGCTCT
9070	9080	9090	9097	10
CTGGCTAACT	AGGGAACCCA	CTGCTTAAGC	CTCAATA	AAGCTTGCCT
20	30	40	50	60
TGAGTGCTTC	AAGTAGTGTG	TGCCCGTCTG	TTGTGTGACT	CTGGTAACTA
70	80	90	100	110
GAGATCCCTC	AGACCCTTTT	AGTCAGTGTG	GAAAATCTCT	AGCAGTGGCG
120	130	140	150	159
CCCGAACAGG	GACTTGAAAG	CGAAAGGGAA	ACCAGAGGAG	CTCTCTCGA

18. The purified recombinant DNA of claim 17, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

19. A method of using the purified recombinant DNA of claim 17 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

20. The method of claim 19, wherein the biological fluid is blood.

21. A method of using the purified recombinant DNA of claim 18 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

22. The method of claim 21, wherein the biological fluid is blood.

25. A method for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA.

27. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

28. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

29. A method for preparing HIV-1 RNA for detecting the presence of

HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA.

30. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

31. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

32. A method for preparing HIV-1 RNA for detecting the presence of

HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) isolating HIV-1 virions from the cell-free supernatant; and

(c) disrupting the virions to release HIV-1 RNA.

33. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

34. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

35. A purified fragment of the recombinant DNA of claim 17, wherein said fragment comprises the sequence: CTCAATAAAGCTTGCCTTG.

36. The purified fragment of claim 35, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

37. A method of using the purified fragment of claim 35 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 35 and detecting hybridization between the HIV-1 RNA and the purified fragment.

38. The method of claim 37, wherein the biological fluid is blood.

39. A method of using the purified fragment of claim 36 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 36 and detecting hybridization between the HIV-1 RNA and the purified fragment.

40. The method of claim 39, wherein the biological fluid is blood.

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc Alizon et al.

Application No.: 08/308,219

Filed: September 19,1994

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Group Art Unit: 1637

Examiner: Jeffrey N. Fredman

Confirmation No.: 4832

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT OF CLAUDINE AXLER-BLIN
(Being Added As An Inventor)

I have read U.S. application Serial No. 08/308,219.

I am informed that I was not named as an inventor in application Serial No. 08/308,219 when the application was filed in the U.S. Patent and Trademark Office.

I have been informed that the claims in U.S. application Serial No. 08/308,219 have been amended by adding claims 17-22, 25, and 27-40 to the application.

I am informed that a copy of claims 17-22, 25, and 27-40 is attached hereto.

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I understand that I am being added as an inventor to U.S. application Serial No. 08/308,219.

I have been informed that my addition as an inventor to U.S. application Serial No. 08/308,219 is necessitated by the amendment of the claims by adding claims 17-22, 25, and 27-40 to the application.

The inventorship error resulting from the amendment of the claims by adding claims 17-22, 25, and 27-40 to U.S. application Serial No. 08/308,219 occurred without deceptive intention on my part.

I hereby declare that all statements made of my own knowledge and belief are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: Claudine Axler-Blin

Date: 26 Mai 2006

U.S. Patent Application No. 08/308,219
Filed: September 19, 1994
Inventors: Marc ALIZON et al.
Div. of 07/158,652 (02/22/88);
Div. of 06/771,248 (08/30/85);
CIP of 07/999,410 (12/31/92);
Cont. of 07/499,210 (03/19/90);
Cont of 06/771,230 (08/30/85);
CIP of 06/706,562 (02/28/85)'
CIP of 06/558,109 (12/5/83)
DI No.: 84-37
Our Reference: 03495.0010-20000

Pending Claims

17. A purified recombinant DNA of human immunodeficiency virus type 1 (HIV-1), wherein the DNA comprises the sequence:

8570	8580	8590	8600	8610
GGGGGACTGG	AAGGGCTAAT	TCACTCCCAA	CGAAGACAAG	ATATCCTTGA
8620	8630	8640	8650	8660
TCTGTGGATC	TACCACACAC	AAGGCTACTT	CCCTGATTGG	CAGAACTACA
8670	8680	8690	8700	8710
CACCAGGGCC	AGGGGTCAGA	TATCCACTGA	CCTTTGGATG	GTGCTACAAG
8720	8730	8740	8750	8760
CTAGTACCAG	TTGAGCCAGA	TAAGGTAGAA	GAGGCCAATA	AAGGAGAGAA
8770	8780	8790	8800	8810
CACCAGCTTG	TTACACCCTG	TGAGCCTGCA	TGGAATGGAT	GACCCTGAGA
8820	8830	8840	8850	8860
GAGAAGTGTT	AGAGTGGAGG	TTTGACAGCC	GCCTAGCATT	TCATCACGTG
8870	8880	8890	8900	8910
GCCCGAGAGC	TGCATCCGGA	GTACTTCAAG	AACTGCTGAC	ATCGAGCTTG
8920	8930	8940	8950	8960
CTACAAGGGA	CTTTCCGCTG	GGGACTTTCC	AGGGAGGCGT	GGCCTGGGCG
8970	8980	8990	9000	9010
GAACTGGGGA	GTGGCGAGCC	CTCAGATGCT	GCATATAAGC	AGCTGCTTTT

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      9020        9030        9040        9050        9060
TGCCTGTACT  GGGTCTCTCT  GGTTAGACCA  GATTTGAGCC TGGGAGCTCT

      9070        9080        9090     9097             10
CTGGCTAACT  AGGGAACCCA  CTGCTTAAGC  CTCAATA      AAGCTTGCCT

        20          30          40          50          60
TGAGTGCTTC  AAGTAGTGTG  TGCCCGTCTG  TTGTGTGACT  CTGGTAACTA
        70          80          90         100         110
GAGATCCCTC  AGACCCTTTT  AGTCAGTGTG  GAAAATCTCT  AGCAGTGGCG

       120         130         140         150        159
CCCGAACAGG  GACTTGAAAG  CGAAAGGGAA  ACCAGAGGAG CTCTCTCGA
```

18. The purified recombinant DNA of claim 17, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

19. A method of using the purified recombinant DNA of claim 17 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

20. The method of claim 19, wherein the biological fluid is blood.

21. A method of using the purified recombinant DNA of claim 18 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

22. The method of claim 21, wherein the biological fluid is blood.

25. A method for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA.

27. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

28. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

29. A method for preparing HIV-1 RNA for detecting the presence of

HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA.

30. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

31. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

32. A method for preparing HIV-1 RNA for detecting the presence of

HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) isolating HIV-1 virions from the cell-free supernatant; and

(c) disrupting the virions to release HIV-1 RNA.

33. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

34. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

35. A purified fragment of the recombinant DNA of claim 17, wherein said fragment comprises the sequence: CTCAATAAAGCTTGCCTTG.

36. The purified fragment of claim 35, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

37. A method of using the purified fragment of claim 35 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 35 and detecting hybridization between the HIV-1 RNA and the purified fragment.

38. The method of claim 37, wherein the biological fluid is blood.

39. A method of using the purified fragment of claim 36 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 36 and detecting hybridization between the HIV-1 RNA and the purified fragment.

40. The method of claim 39, wherein the biological fluid is blood.

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc Alizon et al.

Application No.: 08/308,219

Filed: September 19,1994

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Group Art Unit: 1637

Examiner: Jeffrey N. Fredman

Confirmation No.: 4832

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT OF FRANÇOISE REY
(Being Added As An Inventor)

I have read U.S. application Serial No. 08/308,219.

I am informed that I was not named as an inventor in application Serial No. 08/308,219 when the application was filed in the U.S. Patent and Trademark Office.

I have been informed that the claims in U.S. application Serial No. 08/308,219 have been amended by adding claims 17-22, 25, and 27-40 to the application.

I am informed that a copy of claims 17-22, 25, and 27-40 is attached hereto.

I have read claims 17-22, 25, and 27-40, which I am informed were added to U.S. application Serial No. 08/308,219 to claim previously unclaimed subject matter.

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I have been informed that my addition as an inventor to U.S. application Serial No. 08/308,219 is necessitated by the amendment of the claims by adding claims 17-22, 25, and 27-40 to the application.

The inventorship error resulting from the amendment of the claims by adding claims 17-22, 25, and 27-40 to U.S. application Serial No. 08/308,219 occurred without deceptive intention on my part.

I hereby declare that all statements made of my own knowledge and belief are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: _____

Date: 23 March 2006

U.S. Patent Application No. 08/308,219
Filed: September 19, 1994
Inventors: Marc ALIZON et al.
Div. of 07/158,652 (02/22/88);
Div. of 06/771,248 (08/30/85);
CIP of 07/999,410 (12/31/92);
Cont. of 07/499,210 (03/19/90);
Cont of 06/771,230 (08/30/85);
CIP of 06/706,562 (02/28/85)'
CIP of 06/558,109 (12/5/83)
DI No.: 84-37
Our Reference: 03495.0010-20000

Pending Claims

17. A purified recombinant DNA of human immunodeficiency virus type 1 (HIV-1), wherein the DNA comprises the sequence:

8570	8580	8590	8600	8610
GGGGGACTGG	AAGGGCTAAT	TCACTCCCAA	CGAAGACAAG	ATATCCTTGA
8620	8630	8640	8650	8660
TCTGTGGATC	TACCACACAC	AAGGCTACTT	CCCTGATTGG	CAGAACTACA
8670	8680	8690	8700	8710
CACCAGGGCC	AGGGGTCAGA	TATCCACTGA	CCTTTGGATG	GTGCTACAAG
8720	8730	8740	8750	8760
CTAGTACCAG	TTGAGCCAGA	TAAGGTAGAA	GAGGCCAATA	AAGGAGAGAA
8770	8780	8790	8800	8810
CACCAGCTTG	TTACACCCTG	TGAGCCTGCA	TGGAATGGAT	GACCCTGAGA
8820	8830	8840	8850	8860
GAGAAGTGTT	AGAGTGGAGG	TTTGACAGCC	GCCTAGCATT	TCATCACGTG
8870	8880	8890	8900	8910
GCCCGAGAGC	TGCATCCGGA	GTACTTCAAG	AACTGCTGAC	ATCGAGCTTG
8920	8930	8940	8950	8960
CTACAAGGGA	CTTTCCGCTG	GGGACTTTCC	AGGGAGGCGT	GGCCTGGGCG
8970	8980	8990	9000	9010
GAACTGGGGA	GTGGCGAGCC	CTCAGATGCT	GCATATAAGC	AGCTGCTTTT

```
      9020         9030         9040         9050         9060
TGCCTGTACT  GGGTCTCTCT  GGTTAGACCA  GATTTGAGCC TGGGAGCTCT

      9070         9080         9090    9097              10
CTGGCTAACT  AGGGAACCCA  CTGCTTAAGC  CTCAATA      AAGCTTGCCT

        20           30           40           50           60
TGAGTGCTTC  AAGTAGTGTG  TGCCCGTCTG  TTGTGTGACT  CTGGTAACTA
        70           80           90          100          110
GAGATCCCTC  AGACCCTTTT  AGTCAGTGTG  GAAAATCTCT  AGCAGTGGCG

       120          130          140          150          159
CCCGAACAGG  GACTTGAAAG  CGAAAGGGAA  ACCAGAGGAG CTCTCTCGA
```

18. The purified recombinant DNA of claim 17, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

19. A method of using the purified recombinant DNA of claim 17 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

20. The method of claim 19, wherein the biological fluid is blood.

21. A method of using the purified recombinant DNA of claim 18 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

22. The method of claim 21, wherein the biological fluid is blood.

25. A method for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA.

27. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

28. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

29. A method for preparing HIV-1 RNA for detecting the presence of

HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA.

30. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

31. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

32. A method for preparing HIV-1 RNA for detecting the presence of

HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) isolating HIV-1 virions from the cell-free supernatant; and

(c) disrupting the virions to release HIV-1 RNA.

33. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

34. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

35. A purified fragment of the recombinant DNA of claim 17, wherein said fragment comprises the sequence: CTCAATAAAGCTTGCCTTG.

36. The purified fragment of claim 35, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

37. A method of using the purified fragment of claim 35 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 35 and detecting hybridization between the HIV-1 RNA and the purified fragment.

38. The method of claim 37, wherein the biological fluid is blood.

39. A method of using the purified fragment of claim 36 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 36 and detecting hybridization between the HIV-1 RNA and the purified fragment.

40. The method of claim 39, wherein the biological fluid is blood.

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc Alizon et al.

Application No.: 08/308,219

Filed: September 19,1994

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Group Art Unit: 1637

Examiner: Jeffrey N. Fredman

Confirmation No.: 4832

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT OF MARIE-THERESE NUGEYRE
(Being Added As An Inventor)

I have read U.S. application Serial No. 08/308,219.

I am informed that I was not named as an inventor in application Serial No. 08/308,219 when the application was filed in the U.S. Patent and Trademark Office.

I have been informed that the claims in U.S. application Serial No. 08/308,219 have been amended by adding claims 17-22, 25, and 27-40 to the application.

I am informed that a copy of claims 17-22, 25, and 27-40 is attached hereto.

I have read claims 17-22, 25, and 27-40, which I am informed were added to U.S. application Serial No. 08/308,219 to claim previously unclaimed subject matter.

I understand that I am being added as an inventor to U.S. application Serial No. 08/308,219.

I have been informed that my addition as an inventor to U.S. application Serial No. 08/308,219 is necessitated by the amendment of the claims by adding claims 17-22, 25, and 27-40 to the application.

The inventorship error resulting from the amendment of the claims by adding claims 17-22, 25, and 27-40 to U.S. application Serial No. 08/308,219 occurred without deceptive intention on my part.

I hereby declare that all statements made of my own knowledge and belief are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: _____

Date: May 29 2006

U.S. Patent Application No. 08/308,219
Filed: September 19, 1994
Inventors: Marc ALIZON et al.
Div. of 07/158,652 (02/22/88);
Div. of 06/771,248 (08/30/85);
CIP of 07/999,410 (12/31/92);
Cont. of 07/499,210 (03/19/90);
Cont of 06/771,230 (08/30/85);
CIP of 06/706,562 (02/28/85)'
CIP of 06/558,109 (12/5/83)
DI No.: 84-37
Our Reference: 03495.0010-20000

Pending Claims

17. A purified recombinant DNA of human immunodeficiency virus type 1 (HIV-1), wherein the DNA comprises the sequence:

8570	8580	8590	8600	8610
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8620	8630	8640	8650	8660
TCTGTGGATC	TACCACACAC	AAGGCTACTT	CCCTGATTGG	CAGAACTACA
8670	8680	8690	8700	8710
CACCAGGGCC	AGGGGTCAGA	TATCCACTGA	CCTTTGGATG	GTGCTACAAG
8720	8730	8740	8750	8760
CTAGTACCAG	TTGAGCCAGA	TAAGGTAGAA	GAGGCCAATA	AAGGAGAGAA
8770	8780	8790	8800	8810
CACCAGCTTG	TTACACCCTG	TGAGCCTGCA	TGGAATGGAT	GACCCTGAGA
8820	8830	8840	8850	8860
GAGAAGTGTT	AGAGTGGAGG	TTTGACAGCC	GCCTAGCATT	TCATCACGTG
8870	8880	8890	8900	8910
GCCCGAGAGC	TGCATCCGGA	GTACTTCAAG	AACTGCTGAC	ATCGAGCTTG
8920	8930	8940	8950	8960
CTACAAGGGA	CTTTCCGCTG	GGGACTTTCC	AGGGAGGCGT	GGCCTGGGCG
8970	8980	8990	9000	9010
GAACTGGGGA	GTGGCGAGCC	CTCAGATGCT	GCATATAAGC	AGCTGCTTTT

```
      9020         9030         9040         9050         9060
TGCCTGTACT  GGGTCTCTCT  GGTTAGACCA  GATTTGAGCC TGGGAGCTCT

      9070         9080         9090     9097             10
CTGGCTAACT  AGGGAACCCA  CTGCTTAAGC  CTCAATA      AAGCTTGCCT

        20           30           40           50           60
TGAGTGCTTC  AAGTAGTGTG  TGCCCGTCTG  TTGTGTGACT  CTGGTAACTA
        70           80           90          100          110
GAGATCCCTC  AGACCCTTTT  AGTCAGTGTG  GAAAATCTCT  AGCAGTGGCG

       120          130          140          150          159
CCCGAACAGG  GACTTGAAAG  CGAAAGGGAA  ACCAGAGGAG CTCTCTCGA
```

18. The purified recombinant DNA of claim 17, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

19. A method of using the purified recombinant DNA of claim 17 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

20. The method of claim 19, wherein the biological fluid is blood.

21. A method of using the purified recombinant DNA of claim 18 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

22. The method of claim 21, wherein the biological fluid is blood.

25. A method for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA.

27. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

28. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

29. A method for preparing HIV-1 RNA for detecting the presence of
HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA.

30. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

31. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

32. A method for preparing HIV-1 RNA for detecting the presence of
HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) isolating HIV-1 virions from the cell-free supernatant; and

(c) disrupting the virions to release HIV-1 RNA.

33. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

34. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

35. A purified fragment of the recombinant DNA of claim 17, wherein said fragment comprises the sequence: CTCAATAAAGCTTGCCTTG.

36. The purified fragment of claim 35, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

37. A method of using the purified fragment of claim 35 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 35 and detecting hybridization between the HIV-1 RNA and the purified fragment.

38. The method of claim 37, wherein the biological fluid is blood.

39. A method of using the purified fragment of claim 36 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 36 and detecting hybridization between the HIV-1 RNA and the purified fragment.

40. The method of claim 39, wherein the biological fluid is blood.

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc Alizon et al.

Application No.: 08/308,219

Filed: September 19,1994

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Group Art Unit: 1637

Examiner: Jeffrey N. Fredman

Confirmation No.: 4832

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT ON BEHALF OF JACQUELINE GRUEST
(Being Added As An Inventor)

I, JACQUES GRUEST, am the heir of the estate of JACQUELINE GRUEST, who is deceased.

I have been informed that Jacqueline Gruest was not named as an inventor in application Serial No. 08/308,219 when the application was filed in the U.S. Patent and Trademark Office.

I have been informed that the claims in U.S. application Serial No. 08/308,219 have been amended by adding claims 17-22, 25, and 27-40 to the application.

I have been informed that a copy of claims 17-22, 25, and 27-40 is attached hereto.

I have been informed that claims 17-22, 25, and 27-40 were added to U.S. application Serial No. 08/308,219 to claim previously unclaimed subject matter.

I have been informed that Jacqueline Gruest is being added as an inventor to U.S. application Serial No. 08/308,219.

I have been informed that the addition of Jacqueline Gruest as an inventor to U.S. application Serial No. 08/308,219 is necessitated by the amendment of the claims by adding claims 17-22, 25, and 27-40 to the application.

On information and belief, the inventorship error resulting from the amendment of the claims by adding claims 17-22, 25, and 27-40 to U.S. application Serial No. 08/308,219 occurred without deceptive intention on the part of Jacqueline Gruest.

I hereby declare that all statements made of my own knowledge and belief are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: _____

JACQUES GRUEST
Heir of the Estate of Jacqueline Gruest

Date: 25.05.2006

U.S. Patent Application No. 08/308,219
Filed: September 19, 1994
Inventors: Marc ALIZON et al.
Div. of 07/158,652 (02/22/88);
Div. of 06/771,248 (08/30/85);
CIP of 07/999,410 (12/31/92);
Cont. of 07/499,210 (03/19/90);
Cont of 06/771,230 (08/30/85);
CIP of 06/706,562 (02/28/85)'
CIP of 06/558,109 (12/5/83)
DI No.: 84-37
Our Reference: 03495.0010-20000

Pending Claims

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TCTGTGGATC	TACCACACAC	AAGGCTACTT	CCCTGATTGG	CAGAACTACA
8670	8680	8690	8700	8710
CACCAGGGCC	AGGGGTCAGA	TATCCACTGA	CCTTTGGATG	GTGCTACAAG
8720	8730	8740	8750	8760
CTAGTACCAG	TTGAGCCAGA	TAAGGTAGAA	GAGGCCAATA	AAGGAGAGAA
8770	8780	8790	8800	8810
CACCAGCTTG	TTACACCCTG	TGAGCCTGCA	TGGAATGGAT	GACCCTGAGA
8820	8830	8840	8850	8860
GAGAAGTGTT	AGAGTGGAGG	TTTGACAGCC	GCCTAGCATT	TCATCACGTG
8870	8880	8890	8900	8910
GCCCGAGAGC	TGCATCCGGA	GTACTTCAAG	AACTGCTGAC	ATCGAGCTTG
8920	8930	8940	8950	8960
CTACAAGGGA	CTTTCCGCTG	GGGACTTTCC	AGGGAGGCGT	GGCCTGGGCG
8970	8980	8990	9000	9010
GAACTGGGGA	GTGGCGAGCC	CTCAGATGCT	GCATATAAGC	AGCTGCTTTT

```
      9020        9030        9040        9050        9060
TGCCTGTACT  GGGTCTCTCT  GGTTAGACCA  GATTTGAGCC TGGGAGCTCT

      9070        9080        9090     9097           10
CTGGCTAACT  AGGGAACCCA  CTGCTTAAGC  CTCAATA     AAGCTTGCCT

        20          30          40          50          60
TGAGTGCTTC  AAGTAGTGTG  TGCCCGTCTG  TTGTGTGACT  CTGGTAACTA
        70          80          90         100         110
GAGATCCCTC  AGACCCTTTT  AGTCAGTGTG  GAAAATCTCT  AGCAGTGGCG

       120         130         140         150       159
CCCGAACAGG  GACTTGAAAG  CGAAAGGGAA  ACCAGAGGAG CTCTCTCGA
```

18. The purified recombinant DNA of claim 17, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

19. A method of using the purified recombinant DNA of claim 17 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

20. The method of claim 19, wherein the biological fluid is blood.

21. A method of using the purified recombinant DNA of claim 18 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

22. The method of claim 21, wherein the biological fluid is blood.

25. A method for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA.

27. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

28. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

29. A method for preparing HIV-1 RNA for detecting the presence of
HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA.

30. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

31. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

32. A method for preparing HIV-1 RNA for detecting the presence of
HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) isolating HIV-1 virions from the cell-free supernatant; and

(c) disrupting the virions to release HIV-1 RNA.

33. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

34. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

35. A purified fragment of the recombinant DNA of claim 17, wherein said fragment comprises the sequence: CTCAATAAAGCTTGCCTTG.

36. The purified fragment of claim 35, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

37. A method of using the purified fragment of claim 35 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 35 and detecting hybridization between the HIV-1 RNA and the purified fragment.

38. The method of claim 37, wherein the biological fluid is blood.

39. A method of using the purified fragment of claim 36 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 36 and detecting hybridization between the HIV-1 RNA and the purified fragment.

40. The method of claim 39, wherein the biological fluid is blood.

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc Alizon et al.

Application No.: 08/308,219

Filed: September 19,1994

Group Art Unit: 1637

Examiner: Jeffrey N. Fredman

Confirmation No.: 4832

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT OF CHARLES DAUGUET
(Being Added As An Inventor)

I have read U.S. application Serial No. 08/308,219.

I am informed that I was not named as an inventor in application Serial No. 08/308,219 when the application was filed in the U.S. Patent and Trademark Office.

I have been informed that the claims in U.S. application Serial No. 08/308,219 have been amended by adding claims 17-22, 25, and 27-40 to the application.

I am informed that a copy of claims 17-22, 25, and 27-40 is attached hereto.

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The inventorship error resulting from the amendment of the claims by adding claims 17-22, 25, and 27-40 to U.S. application Serial No. 08/308,219 occurred without deceptive intention on my part.

I hereby declare that all statements made of my own knowledge and belief are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: Charles Dougherty

Date: 26 Mai 2006

U.S. Patent Application No. 08/308,219
Filed: September 19, 1994
Inventors: Marc ALIZON et al.
Div. of 07/158,652 (02/22/88);
Div. of 06/771,248 (08/30/85);
CIP of 07/999,410 (12/31/92);
Cont. of 07/499,210 (03/19/90);
Cont of 06/771,230 (08/30/85);
CIP of 06/706,562 (02/28/85)'
CIP of 06/558,109 (12/5/83)
DI No.: 84-37
Our Reference: 03495.0010-20000

Pending Claims

17. A purified recombinant DNA of human immunodeficiency virus type 1 (HIV-1), wherein the DNA comprises the sequence:

8570	8580	8590	8600	8610
GGGGGACTGG	AAGGGCTAAT	TCACTCCCAA	CGAAGACAAG	ATATCCTTGA
8620	8630	8640	8650	8660
TCTGTGGATC	TACCACACAC	AAGGCTACTT	CCCTGATTGG	CAGAACTACA
8670	8680	8690	8700	8710
CACCAGGGCC	AGGGGTCAGA	TATCCACTGA	CCTTTGGATG	GTGCTACAAG
8720	8730	8740	8750	8760
CTAGTACCAG	TTGAGCCAGA	TAAGGTAGAA	GAGGCCAATA	AAGGAGAGAA
8770	8780	8790	8800	8810
CACCAGCTTG	TTACACCCTG	TGAGCCTGCA	TGGAATGGAT	GACCCTGAGA
8820	8830	8840	8850	8860
GAGAAGTGTT	AGAGTGGAGG	TTTGACAGCC	GCCTAGCATT	TCATCACGTG
8870	8880	8890	8900	8910
GCCCGAGAGC	TGCATCCGGA	GTACTTCAAG	AACTGCTGAC	ATCGAGCTTG
8920	8930	8940	8950	8960
CTACAAGGGA	CTTTCCGCTG	GGGACTTTCC	AGGGAGGCGT	GGCCTGGGCG
8970	8980	8990	9000	9010
GAACTGGGGA	GTGGCGAGCC	CTCAGATGCT	GCATATAAGC	AGCTGCTTTT

```
      9020        9030        9040        9050        9060
TGCCTGTACT  GGGTCTCTCT  GGTTAGACCA  GATTTGAGCC TGGGAGCTCT

      9070        9080        9090     9097            10
CTGGCTAACT  AGGGAACCCA  CTGCTTAAGC  CTCAATA     AAGCTTGCCT

        20          30          40          50          60
TGAGTGCTTC  AAGTAGTGTG  TGCCCGTCTG  TTGTGTGACT  CTGGTAACTA
        70          80          90         100         110
GAGATCCCTC  AGACCCTTTT  AGTCAGTGTG  GAAAATCTCT  AGCAGTGGCG

       120         130         140         150       159
CCCGAACAGG  GACTTGAAAG  CGAAAGGGAA  ACCAGAGGAG CTCTCTCGA
```

18. The purified recombinant DNA of claim 17, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

19. A method of using the purified recombinant DNA of claim 17 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

20. The method of claim 19, wherein the biological fluid is blood.

21. A method of using the purified recombinant DNA of claim 18 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

22. The method of claim 21, wherein the biological fluid is blood.

25. A method for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA.

27. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

28. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

29. A method for preparing HIV-1 RNA for detecting the presence of
HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA.

30. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

31. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

32. A method for preparing HIV-1 RNA for detecting the presence of
HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) isolating HIV-1 virions from the cell-free supernatant; and

(c) disrupting the virions to release HIV-1 RNA.

33. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

34. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

35. A purified fragment of the recombinant DNA of claim 17, wherein said fragment comprises the sequence: CTCAATAAAGCTTGCCTTG.

36. The purified fragment of claim 35, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

37. A method of using the purified fragment of claim 35 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 35 and detecting hybridization between the HIV-1 RNA and the purified fragment.

38. The method of claim 37, wherein the biological fluid is blood.

39. A method of using the purified fragment of claim 36 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 36 and detecting hybridization between the HIV-1 RNA and the purified fragment.

40. The method of claim 39, wherein the biological fluid is blood.

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc Alizon et al.

Application No.: 08/308,219

Filed: September 19,1994

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Group Art Unit: 1637

Examiner: Jeffrey N. Fredman

Confirmation No.: 4832

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT OF WILLY ROZENBAUM
(Being Added As An Inventor)

I have read U.S. application Serial No. 08/308,219.

I am informed that I was not named as an inventor in application Serial No. 08/308,219 when the application was filed in the U.S. Patent and Trademark Office.

I have been informed that the claims in U.S. application Serial No. 08/308,219 have been amended by adding claims 17-22, 25, and 27-40 to the application.

I am informed that a copy of claims 17-22, 25, and 27-40 is attached hereto.

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I hereby declare that all statements made of my own knowledge and belief are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: _____
Willy Rozenbaum

Date: 25 May 2006

U.S. Patent Application No. 08/308,219
Filed: September 19, 1994
Inventors: Marc ALIZON et al.
Div. of 07/158,652 (02/22/88);
Div. of 06/771,248 (08/30/85);
CIP of 07/999,410 (12/31/92);
Cont. of 07/499,210 (03/19/90);
Cont of 06/771,230 (08/30/85);
CIP of 06/706,562 (02/28/85)'
CIP of 06/558,109 (12/5/83)
DI No.: 84-37
Our Reference: 03495.0010-20000

Pending Claims

17. A purified recombinant DNA of human immunodeficiency virus type 1 (HIV-1), wherein the DNA comprises the sequence:

8570	8580	8590	8600	8610
GGGGGACTGG	AAGGGCTAAT	TCACTCCCAA	CGAAGACAAG	ATATCCTTGA
8620	8630	8640	8650	8660
TCTGTGGATC	TACCACACAC	AAGGCTACTT	CCCTGATTGG	CAGAACTACA
8670	8680	8690	8700	8710
CACCAGGGCC	AGGGGTCAGA	TATCCACTGA	CCTTTGGATG	GTGCTACAAG
8720	8730	8740	8750	8760
CTAGTACCAG	TTGAGCCAGA	TAAGGTAGAA	GAGGCCAATA	AAGGAGAGAA
8770	8780	8790	8800	8810
CACCAGCTTG	TTACACCCTG	TGAGCCTGCA	TGGAATGGAT	GACCCTGAGA
8820	8830	8840	8850	8860
GAGAAGTGTT	AGAGTGGAGG	TTTGACAGCC	GCCTAGCATT	TCATCACGTG
8870	8880	8890	8900	8910
GCCCGAGAGC	TGCATCCGGA	GTACTTCAAG	AACTGCTGAC	ATCGAGCTTG
8920	8930	8940	8950	8960
CTACAAGGGA	CTTTCCGCTG	GGGACTTTCC	AGGGAGGCGT	GGCCTGGGCG
8970	8980	8990	9000	9010
GAACTGGGGA	GTGGCGAGCC	CTCAGATGCT	GCATATAAGC	AGCTGCTTTT

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      9020         9030         9040         9050         9060
TGCCTGTACT  GGGTCTCTCT  GGTTAGACCA  GATTTGAGCC TGGGAGCTCT

      9070         9080         9090     9097             10
CTGGCTAACT  AGGGAACCCA  CTGCTTAAGC  CTCAATA      AAGCTTGCCT

        20           30           40           50           60
TGAGTGCTTC  AAGTAGTGTG  TGCCCGTCTG  TTGTGTGACT  CTGGTAACTA
        70           80           90          100          110
GAGATCCCTC  AGACCCTTTT  AGTCAGTGTG  GAAAATCTCT  AGCAGTGGCG

       120          130          140          150        159
CCCGAACAGG  GACTTGAAAG  CGAAAGGGAA  ACCAGAGGAG CTCTCTCGA
```

18. The purified recombinant DNA of claim 17, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

19. A method of using the purified recombinant DNA of claim 17 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

20. The method of claim 19, wherein the biological fluid is blood.

21. A method of using the purified recombinant DNA of claim 18 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

22. The method of claim 21, wherein the biological fluid is blood.

25. A method for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA.

27. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

28. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

29. A method for preparing HIV-1 RNA for detecting the presence of
HIV-1 RNA comprising:

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30. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

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32. A method for preparing HIV-1 RNA for detecting the presence of
HIV-1 RNA comprising:

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(b) isolating HIV-1 virions from the cell-free supernatant; and

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35. A purified fragment of the recombinant DNA of claim 17, wherein said fragment comprises the sequence: CTCAATAAAGCTTGCCTTG.

36. The purified fragment of claim 35, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

37. A method of using the purified fragment of claim 35 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

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PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc Alizon et al.

Application No.: 08/308,219

Filed: September 19,1994

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Group Art Unit: 1637

Examiner: Jeffrey N. Fredman

Confirmation No.: 4832

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT OF FRANÇOISE BRUN-VEZINET
(Being Added As An Inventor)

I have read U.S. application Serial No. 08/308,219.

I am informed that I was not named as an inventor in application Serial No. 08/308,219 when the application was filed in the U.S. Patent and Trademark Office.

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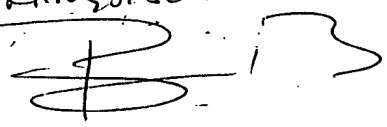
FRANÇOISE BRUN-VEZINET

By: 

Date: 30/05/06

U.S. Patent Application No. 08/308,219
Filed: September 19, 1994
Inventors: Marc ALIZON et al.
Div. of 07/158,652 (02/22/88);
Div. of 06/771,248 (08/30/85);
CIP of 07/999,410 (12/31/92);
Cont. of 07/499,210 (03/19/90);
Cont of 06/771,230 (08/30/85);
CIP of 06/706,562 (02/28/85)'
CIP of 06/558,109 (12/5/83)
DI No.: 84-37
Our Reference: 03495.0010-20000

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8670	8680	8690	8700	8710
CACCAGGGCC	AGGGGTCAGA	TATCCACTGA	CCTTTGGATG	GTGCTACAAG
8720	8730	8740	8750	8760
CTAGTACCAG	TTGAGCCAGA	TAAGGTAGAA	GAGGCCAATA	AAGGAGAGAA
8770	8780	8790	8800	8810
CACCAGCTTG	TTACACCCTG	TGAGCCTGCA	TGGAATGGAT	GACCCTGAGA
8820	8830	8840	8850	8860
GAGAAGTGTT	AGAGTGGAGG	TTTGACAGCC	GCCTAGCATT	TCATCACGTG
8870	8880	8890	8900	8910
GCCCGAGAGC	TGCATCCGGA	GTACTTCAAG	AACTGCTGAC	ATCGAGCTTG
8920	8930	8940	8950	8960
CTACAAGGGA	CTTTCCGCTG	GGGACTTTCC	AGGGAGGCGT	GGCCTGGGCG
8970	8980	8990	9000	9010
GAACTGGGGA	GTGGCGAGCC	CTCAGATGCT	GCATATAAGC	AGCTGCTTTT

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      9020         9030         9040         9050         9060
TGCCTGTACT   GGGTCTCTCT   GGTTAGACCA   GATTTGAGCC TGGGAGCTCT

      9070         9080         9090     9097             10
CTGGCTAACT   AGGGAACCCA   CTGCTTAAGC   CTCAATA      AAGCTTGCCT

        20           30           40           50           60
TGAGTGCTTC   AAGTAGTGTG   TGCCCGTCTG   TTGTGTGACT   CTGGTAACTA
        70           80           90          100          110
GAGATCCCTC   AGACCCTTTT   AGTCAGTGTG   GAAAATCTCT   AGCAGTGGCG

       120          130          140          150          159
CCCGAACAGG   GACTTGAAAG   CGAAAGGGAA   ACCAGAGGAG CTCTCTCGA
```

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(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

20. The method of claim 19, wherein the biological fluid is blood.

28. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

29. A method for preparing HIV-1 RNA for detecting the presence of
HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA.

30. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

31. The method of claim 29, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

32. A method for preparing HIV-1 RNA for detecting the presence of
HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

21. A method of using the purified recombinant DNA of claim 18 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

22. The method of claim 21, wherein the biological fluid is blood.

25. A method for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA.

27. The method of claim 25, wherein the presence of HIV-1 RNA is detected by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

(b) isolating HIV-1 virions from the cell-free supernatant; and

(c) disrupting the virions to release HIV-1 RNA.

33. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

34. The method of claim 32, further comprising detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

35. A purified fragment of the recombinant DNA of claim 17, wherein said fragment comprises the sequence: CTCAATAAAGCTTGCCTTG.

36. The purified fragment of claim 35, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

37. A method of using the purified fragment of claim 35 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 35 and detecting hybridization between the HIV-1 RNA and the purified fragment.

38. The method of claim 37, wherein the biological fluid is blood.

39. A method of using the purified fragment of claim 36 for detecting the presence of HIV-1 RNA comprising:

(a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;

(b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA; and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified fragment of claim 36 and detecting hybridization between the HIV-1 RNA and the purified fragment.

40. The method of claim 39, wherein the biological fluid is blood.

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc Alizon et al.

Application No.: 08/308,219

Filed: September 19,1994

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Group Art Unit: 1637

Examiner: Jeffrey N. Fredman

Confirmation No.: 4832

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SUBMISSION UNDER 37 C.F.R. § 3.73(b)

Institut Pasteur, duly organized under the laws of France and having its principal place of business at 28, rue du Docteur Roux, 75724 Paris Cedex 15, France, submits that it, together with the United States of America as represented by the Secretary of the Department of Health and Human Services, are the Assignees and owners of 100% of the right, title, and interest in the patent application identified above. Institut Pasteur's ownership interest is evidenced by:

An Assignment from the inventors to Institut Pasteur and Centre Nationale de la Recherche Scientifique, jointly, which was recorded in the Patent and Trademark Office at Reel 016769, Frame 0280, on July 14, 2005; copies of the recorded Assignment and the Notice of Recordation are attached hereto as Exhibit A; and

An Assignment from Centre Nationale de la Recherche Scientifique, having its principal place of business at 3, Rue Michel-Ange, 75794 Paris, Cedex 16, France, to Institut Pasteur, a copy of which is attached hereto as Exhibit B; and

Assignments from Solange Chamaret, Claudine Axler-Blin, Françoise Rey, Marie Therese Nugeyre, Jacqueline Gruest, Charles Dauguet, Willy Rozenbaum, Christine Rouzioux, Françoise Brun-Vezinet, Luc Montagnier, Jean-Claude Chermann, Françoise Barre-Sinoussi, and Pierre Tiollais, who are being added as inventors to the patent application identified above, to Institut Pasteur; copies of these Assignments are included in Exhibit C attached hereto.

The undersigned is authorized to act on behalf of the assignee, Institut Pasteur.

I hereby declare that all statements made of my own knowledge and belief are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

A. Dautry

By: _____
Name: Alice Dautry
Title: President
Assignee: Institut Pasteur

Dated: June 1st, 2006

07-19-2005

103042708

U.S. Department of Commerce
Patent and Trademark Office
Atty. Docket No. 3495.0010-15
Attorney Customer Number: 22,85_

To the Director of the U.S. Patent an
Please record the attached original c

Mail Stop Assignment Recordation Services

1. Name of conveying party(ies):
   1. Marc ALIZON
   2. Pierre SONIGO
   3. Cole STEWART
   4. Oliver DANOS
   5. Simon WAIN-HOBSON

2. Name and address of receiving party(ies):

   1. Institut Pasteur
   25-28, rue du Doctor Roux
   75724 Paris Cedex 15, France

   2. Centre Nationale de la Recherche Scientifique
   15, Quai Anatole France
   75007 Paris, France

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

3. Nature of conveyance:

☒ Assignment ☐ Merger

☐ Security Agreement ☐ Change of Name

☐ Other: [Describe]

Execution Date: February 7, 1986

Additional name(s) & Address(es) attached?

☐ Yes ☒ No

4. Application number(s) or patent number(s): If this document is being filed together with a new application, the execution date of the application:

A. Patent Application Number(s):

1. Appln. No. 06/771,248 (08/30/1985)

B. Patent Number(s):

1. US No. 5,980,900 (11/09/1999)

Additional numbers attached? ☒ Yes ☐ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Salvatore J. Arrigo, Reg. No. 46,063

Internal Address: FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Street Address: 901 New York Avenue, N.W.

City: Washington, D.C.

State: Zip: 20001-4413

6. Total number of applications and registrations involved: 14

7. Total fee (37 CFR 1.21(h) and 3.41): $560 ($40 x 14)

☒ Enclosed (Please charge deficiency to deposit account 06-0916)

☐ Authorized to be charged to deposit account

8. Deposit Account No.: 06-0916

9. Statement and signature

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

07/18/2005 FBYRNE 00000140 5980900
01 FC:8021 560.00 DP

Salvatore J. Arrigo

Signature

7/14/05
Date

Total number of pages including cover sheet, attachments and documents: 3

01/2005

4. Application/Patent Numbers (Continued)

Patent Applications	Issued Patents
2. Appln. No. 07/158,652 (02/22/1998)	2. US No. 5,705,612 (01/06/1998)
3. Appln. No. 08/026,736 (03/04/1993)	3. US No. 6,894,152 (02/25/1994)
4. Appln. No. 08/051,226 (04/23/1993)	4. US No. 6,555,112 (04/29/2003)
5. Appln. No. 08/156,930 (11/24/1993)	5. US No. 6,261,564 (07/17/2001)
6. Appln. No. 08/308,218 (09/19/1994)	6. US No. 6,706,268 (03/16/2004)
7. Appln. No. 08/308,219 (09/19/1994)	
8. Appln. No. 08/475,822 (06/07/1995)	

PATENT OR DESIGN: SOLE OR JOIN

ASSIGNMENT

FOR UNFILED APPLICATION FOR UNITED STATES PATENT

(Sole or Joint Inventors)

FULL NAME(S) AND POST OFFICE ADDRESS(ES) OF INVENTOR(S) (including country)

WHEREAS:

- ALIZON Marc, 71, rue du Cardinal Lemoine 75005 PARIS (France)
- SONIGO Pierre 23, rue Gutemberg 75015 PARIS (France)
- STEWART Cole
  4Bis Villa Denise 92320 CHATILLON (France)
- DANOS Oliver 1, Place Rollet 75015 PARIS (France)
- WAIN-HOBSON Simon 3, rue Jean de la Fontaine
  78180 MONTIGNY LES BRETONNEUX (France)

(hereinafter referred to as ASSIGNOR), have invented and own a certain invention entitled:

TITLE OF INVENTION

CLONED DNA SEQUENCES RELATED TO THE GENOMIC RNA OF LYMPHADENOPATHY-ASSOCIATED VIRUS(LAV) AND... RNA

for which application for Letters Patent of the United States has been executed on ~~even date herewith~~, August 30, 1985,

FULL NAME AND ADDRESS (including country) OF ASSIGNEE

WHEREAS:

INSTITUT PASTEUR
25-28, rue du Dr. Roux
75724 PARIS CEDEX 15 (France) and

CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE
15, Quai Anatole France
75007 PARIS (France)

(hereinafter referred to as ASSIGNEE), is desirous of acquiring the entire interest in, to and under said invention and the United States Letters Patent to be obtained therefor;

NOW, THEREFORE, TO ALL WHOM IT MAY CONCERN: Be it known that in consideration of the payment by ASSIGNEE to ASSIGNOR of the sum of One Dollar ($1.00), the receipt of which is hereby acknowledged, and for other good and valuable consideration, ASSIGNOR hereby sells, assigns and transfers to ASSIGNEE the full and exclusive right, title and interest to said invention and all Letters Patent of the United States to be obtained therefor on said application or any continuation, division, renewal, substitute or reissue thereof for the full term or terms for which the same may be granted.

ASSIGNOR hereby covenants that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this assignment and sale;

ASSIGNOR further covenants that ASSIGNEE will, upon its request, be provided promptly with all pertinent facts and documents relating to said application, said invention and said Letters Patent as may be known and accessible to ASSIGNOR and will testify as to the same in any interference or litigation related thereto and will promptly execute and deliver to ASSIGNEE or its legal representative any and all papers, instruments or affidavits required to apply for, obtain, maintain and enforce said application, said invention and said Letters Patent which may be necessary or desirable to carry out the purposes hereof.

STATE OF SIGNING: If signed in the same country as the date of signing then declaration and oath of the patent or this application.

IN WITNESS WHEREOF, I/We have hereunto set hand and seal this 7-8-1986
(Date of Signing)

SIGNATURE(S) of signature(s) must correspond with the name(s) of the inventor(s) above.

Pierre SONIGO (Signature)

(Signature)

(Signature)

NOTE: No witnessing, notarization or legalization is necessary, but can be included if desired as evidence

ASSIGNMENT

WHEREAS, by virtue of an Assignment recorded in the United States Patent and Trademark Office on Reel 016769, Frames 0280-282, on July 14, 2005, Centre Nationale de la Recherche Scientifique (hereinafter referred to as ASSIGNOR), is the owner of rights, title, and interest in United States Patent Application Serial No. 08/308,219, filed September 19, 1994, (Attorney Docket No. 3495.0010-20), in the name of Marc Alizon, Pierre Sonigo, Cole Stewart, Oliver Danos, and Simon Wain-Hobson and entitled DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1).

WHEREAS, Institut Pasteur (hereinafter referred to as ASSIGNEE), is desirous of acquiring from ASSIGNOR the ASSIGNOR's rights, title, and interest in, to and under the aforesaid patent application and the invention therein in the United States of America and its territories and possessions.

NOW THEREFORE, in consideration of good and valuable consideration, receipt of which from ASSIGNEE is acknowledged by ASSIGNOR, ASSIGNOR hereby sells, assigns, and transfers to the ASSIGNEE, its lawful successors and assigns, all of ASSIGNOR's rights to said invention in the United States, its territories and possessions, and all of ASSIGNOR's rights, title, and interest in and to said United States patent application Serial No. 08/308,219, filed September 19, 1994, and in and to any Letters Patent, which may be granted therefor in the United States, its territories and possessions, and in and to reissues, reexaminations, and extensions thereof.

ASSIGNOR hereby authorizes and requests the Commissioner of Patents and Trademarks of the United States to issue any and all of said Letters Patent, when granted, to said ASSIGNEE, its lawful successors and assigns as the assignee of the entire right, title, and interest in and to the same, for the sole use and enjoyment of said ASSIGNEE, its lawful successors and assigns.

Furthermore, ASSIGNOR agrees that it will communicate to said ASSIGNEE, or its representatives, any facts known to ASSIGNOR respecting said invention, and, at ASSIGNEE's expense, testify in any legal proceedings, sign all lawful papers, execute all reissue, reexamination and extension applications, execute all necessary assignment papers to cause any and all of said Letters Patent to be issued to said ASSIGNEE, its lawful successors and assigns, to obtain and enforce proper protection for said invention in the United States, its territories and possessions.

IN WITNESS WHEREOF, ASSIGNOR has hereunto set its hand this 31st day of May, 2006.

Centre Nationale de la Recherche Scientifique

By: _____

Title: Marc J. LEDOUX Chargé de Mission.

WITNESS: _____

TITLE: Responsable du Pilotage de la Valorisation

Frédéric FOUBERT

CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE
3, rue Michel-Ange
75016 PARIS

JOINT INVENTION
Attorney Docket No. 03495.0010-20

ASSIGNMENT

WHEREAS I, the below named inventor, [hereinafter referred to as Assignor], have made an invention entitled:

DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

for which an application for United States Letters Patent was filed on September 19, 1994 (Application No. 08/308,219); and

WHEREAS, Institut Pasteur, whose post office address is 28, rue du Docteur Roux, 75724 Paris Cedex 15, France (hereinafter referred to as Assignee), is desirous of securing the entire right, title, and interest in and to this invention in the United States, and in and to the application for United States Letters Patent on this invention and the Letters Patent to be issued upon this application;

NOW THEREFORE, be it known that for good and valuable consideration the receipt of which from Assignee is hereby acknowledged, I, as Assignor, have sold, assigned, transferred, and set over, and do hereby sell, assign, transfer, and set over unto the Assignee, its lawful successors and assigns, my entire right, title, and interest in and to this invention, and this application, and all divisions, and continuations thereof, and all Letters Patent of the United States, which may be granted thereon, and all reissues thereof, and I hereby authorize and request the Commissioner of Patents and Trademarks of the United States, whose duty it is to issue patents on applications as described above, to issue all Letters Patent for this invention to Assignee, its successors and assigns, in accordance with the terms of this Assignment;

AND, I HEREBY covenant that I have the full right to convey the interest assigned by this Assignment, and I have not executed and will not execute any agreement in conflict with this Assignment;

AND, I HEREBY further covenant and agree that I will, without further consideration, communicate with Assignee, its successors and assigns, any facts known to me respecting this invention, and testify in any legal proceeding, sign all lawful papers when called upon to do so, execute and deliver any and all papers that may be necessary or desirable to perfect the title to this invention in said Assignee, its successors or assigns, execute all divisional, continuation, and reissue applications, make all rightful oaths and generally do everything possible to aid Assignee, its successors and assigns, to obtain and enforce proper patent protection for this invention in the United States and any foreign country, it being understood that any expense incident to the execution of such papers shall be borne by the Assignee, its successors and assigns.

IN TESTIMONY WHEREOF, I have hereunto set my hand.

S Chamaret
Solange Chamaret

24-05-06
Date

JOINT INVENTION
Attorney Docket No. 03495.0010-20

ASSIGNMENT

WHEREAS I, the below named inventor, [hereinafter referred to as Assignor], have made an invention entitled:

DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

for which an application for United States Letters Patent was filed on September 19, 1994 (Application No. 08/308,219); and

WHEREAS, Institut Pasteur, whose post office address is 28, rue du Docteur Roux, 75724 Paris Cedex 15, France (hereinafter referred to as Assignee), is desirous of securing the entire right, title, and interest in and to this invention in the United States, and in and to the application for United States Letters Patent on this invention and the Letters Patent to be issued upon this application;

NOW THEREFORE, be it known that for good and valuable consideration the receipt of which from Assignee is hereby acknowledged, I, as Assignor, have sold, assigned, transferred, and set over, and do hereby sell, assign, transfer, and set over unto the Assignee, its lawful successors and assigns, my entire right, title, and interest in and to this invention, and this application, and all divisions, and continuations thereof, and all Letters Patent of the United States, which may be granted thereon, and all reissues thereof, and I hereby authorize and request the Commissioner of Patents and Trademarks of the United States, whose duty it is to issue patents on applications as described above, to issue all Letters Patent for this invention to Assignee, its successors and assigns, in accordance with the terms of this Assignment;

AND, I HEREBY covenant that I have the full right to convey the interest assigned by this Assignment, and I have not executed and will not execute any agreement in conflict with this Assignment;

AND, I HEREBY further covenant and agree that I will, without further consideration, communicate with Assignee, its successors and assigns, any facts known to me respecting this invention, and testify in any legal proceeding, sign all lawful papers when called upon to do so, execute and deliver any and all papers that may be necessary or desirable to perfect the title to this invention in said Assignee, its successors or assigns, execute all divisional, continuation, and reissue applications, make all rightful oaths and generally do everything possible to aid Assignee, its successors and assigns, to obtain and enforce proper patent protection for this invention in the United States and any foreign country, it being understood that any expense incident to the execution of such papers shall be borne by the Assignee, its successors and assigns.

IN TESTIMONY WHEREOF, I have hereunto set my hand.

C-Axler-Blin
Claudine Axler-Blin

26 mai 2006.
Date

JOINT INVENTION
Attorney Docket No. 03495.0010-20

ASSIGNMENT

WHEREAS I, the below named inventor, [hereinafter referred to as Assignor], have made an invention entitled:

DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

for which an application for United States Letters Patent was filed on September 19, 1994 (Application No. 08/308,219); and

WHEREAS, Institut Pasteur, whose post office address is 28, rue du Docteur Roux, 75724 Paris Cedex 15, France (hereinafter referred to as Assignee), is desirous of securing the entire right, title, and interest in and to this invention in the United States, and in and to the application for United States Letters Patent on this invention and the Letters Patent to be issued upon this application;

NOW THEREFORE, be it known that for good and valuable consideration the receipt of which from Assignee is hereby acknowledged, I, as Assignor, have sold, assigned, transferred, and set over, and do hereby sell, assign, transfer, and set over unto the Assignee, its lawful successors and assigns, my entire right, title, and interest in and to this invention, and this application, and all divisions, and continuations thereof, and all Letters Patent of the United States, which may be granted thereon, and all reissues thereof, and I hereby authorize and request the Commissioner of Patents and Trademarks of the United States, whose duty it is to issue patents on applications as described above, to issue all Letters Patent for this invention to Assignee, its successors and assigns, in accordance with the terms of this Assignment;

AND, I HEREBY covenant that I have the full right to convey the interest assigned by this Assignment, and I have not executed and will not execute any agreement in conflict with this Assignment;

AND, I HEREBY further covenant and agree that I will, without further consideration, communicate with Assignee, its successors and assigns, any facts known to me respecting this invention, and testify in any legal proceeding, sign all lawful papers when called upon to do so, execute and deliver any and all papers that may be necessary or desirable to perfect the title to this invention in said Assignee, its successors or assigns, execute all divisional, continuation, and reissue applications, make all rightful oaths and generally do everything possible to aid Assignee, its successors and assigns, to obtain and enforce proper patent protection for this invention in the United States and any foreign country, it being understood that any expense incident to the execution of such papers shall be borne by the Assignee, its successors and assigns.

IN TESTIMONY WHEREOF, I have hereunto set my hand.

Françoise Rey

Date

JOINT INVENTION
Attorney Docket No. 03495.0010-20

ASSIGNMENT

WHEREAS I, the below named inventor, [hereinafter referred to as Assignor], have made an invention entitled:

DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

for which an application for United States Letters Patent was filed on September 19, 1994 (Application No. 08/308,219); and

WHEREAS, Institut Pasteur, whose post office address is 28, rue du Docteur Roux, 75724 Paris Cedex 15, France (hereinafter referred to as Assignee), is desirous of securing the entire right, title, and interest in and to this invention in the United States, and in and to the application for United States Letters Patent on this invention and the Letters Patent to be issued upon this application;

NOW THEREFORE, be it known that for good and valuable consideration the receipt of which from Assignee is hereby acknowledged, I, as Assignor, have sold, assigned, transferred, and set over, and do hereby sell, assign, transfer, and set over unto the Assignee, its lawful successors and assigns, my entire right, title, and interest in and to this invention, and this application, and all divisions, and continuations thereof, and all Letters Patent of the United States, which may be granted thereon, and all reissues thereof, and I hereby authorize and request the Commissioner of Patents and Trademarks of the United States, whose duty it is to issue patents on applications as described above, to issue all Letters Patent for this invention to Assignee, its successors and assigns, in accordance with the terms of this Assignment;

AND, I HEREBY covenant that I have the full right to convey the interest assigned by this Assignment, and I have not executed and will not execute any agreement in conflict with this Assignment;

AND, I HEREBY further covenant and agree that I will, without further consideration, communicate with Assignee, its successors and assigns, any facts known to me respecting this invention, and testify in any legal proceeding, sign all lawful papers when called upon to do so, execute and deliver any and all papers that may be necessary or desirable to perfect the title to this invention in said Assignee, its successors or assigns, execute all divisional, continuation, and reissue applications, make all rightful oaths and generally do everything possible to aid Assignee, its successors and assigns, to obtain and enforce proper patent protection for this invention in the United States and any foreign country, it being understood that any expense incident to the execution of such papers shall be borne by the Assignee, its successors and assigns.

IN TESTIMONY WHEREOF, I have hereunto set my hand.

Marie-Therese Nugeyre

May 29 2006
Date

JOINT INVENTION
Attorney Docket No. 03495.0010-20

ASSIGNMENT

WHEREAS, JACQUELINE GRUEST, [hereinafter referred to as Assignor], made an invention entitled:

DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

for which an application for United States Letters Patent was filed on September 19, 1994 (Application No. 08/308,219); and

WHEREAS, Institut Pasteur, whose post office address is 28, rue du Docteur Roux, 75724 Paris Cedex 15, France (hereinafter referred to as Assignee), is desirous of securing the entire right, title, and interest in and to this invention in the United States, and in and to the application for United States Letters Patent on this invention and the Letters Patent to be issued upon this application;

NOW THEREFORE, be it known that for good and valuable consideration the receipt of which from Assignee is hereby acknowledged, I, as Assignor, have sold, assigned, transferred, and set over, and do hereby sell, assign, transfer, and set over unto the Assignee, its lawful successors and assigns, my entire right, title, and interest in and to this invention, and this application, and all divisions, and continuations thereof, and all Letters Patent of the United States, which may be granted thereon, and all reissues thereof, and I hereby authorize and request the Commissioner of Patents and Trademarks of the United States, whose duty it is to issue patents on applications as described above, to issue all Letters Patent for this invention to Assignee, its successors and assigns, in accordance with the terms of this Assignment;

AND, I HEREBY covenant that I have the full right to convey the interest assigned by this Assignment, and I have not executed and will not execute any agreement in conflict with this Assignment;

AND, I HEREBY further covenant and agree that I will, without further consideration, communicate with Assignee, its successors and assigns, any facts known to me respecting this invention, and testify in any legal proceeding, sign all lawful papers when called upon to do so, execute and deliver any and all papers that may be necessary or desirable to perfect the title to this invention in said Assignee, its successors or assigns, execute all divisional, continuation, and reissue applications, make all rightful oaths and generally do everything possible to aid Assignee, its successors and assigns, to obtain and enforce proper patent protection for this invention in the United States and any foreign country, it being understood that any expense incident to the execution of such papers shall be borne by the Assignee, its successors and assigns.

IN TESTIMONY WHEREOF, I have hereunto set my hand.

Jacqueline Gruest
By: Jacques Gruest, Heir to the Estate of Jacqueline Gruest, Deceased

25.05.2006
Date

JOINT INVENTION
Attorney Docket No. 03495.0010-20

ASSIGNMENT

WHEREAS I, the below named inventor, [hereinafter referred to as Assignor], have made an invention entitled:

DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

for which an application for United States Letters Patent was filed on September 19, 1994 (Application No. 08/308,219); and

WHEREAS, Institut Pasteur, whose post office address is 28, rue du Docteur Roux, 75724 Paris Cedex 15, France (hereinafter referred to as Assignee), is desirous of securing the entire right, title, and interest in and to this invention in the United States, and in and to the application for United States Letters Patent on this invention and the Letters Patent to be issued upon this application;

NOW THEREFORE, be it known that for good and valuable consideration the receipt of which from Assignee is hereby acknowledged, I, as Assignor, have sold, assigned, transferred, and set over, and do hereby sell, assign, transfer, and set over unto the Assignee, its lawful successors and assigns, my entire right, title, and interest in and to this invention, and this application, and all divisions, and continuations thereof, and all Letters Patent of the United States, which may be granted thereon, and all reissues thereof, and I hereby authorize and request the Commissioner of Patents and Trademarks of the United States, whose duty it is to issue patents on applications as described above, to issue all Letters Patent for this invention to Assignee, its successors and assigns, in accordance with the terms of this Assignment;

AND, I HEREBY covenant that I have the full right to convey the interest assigned by this Assignment, and I have not executed and will not execute any agreement in conflict with this Assignment;

AND, I HEREBY further covenant and agree that I will, without further consideration, communicate with Assignee, its successors and assigns, any facts known to me respecting this invention, and testify in any legal proceeding, sign all lawful papers when called upon to do so, execute and deliver any and all papers that may be necessary or desirable to perfect the title to this invention in said Assignee, its successors or assigns, execute all divisional, continuation, and reissue applications, make all rightful oaths and generally do everything possible to aid Assignee, its successors and assigns, to obtain and enforce proper patent protection for this invention in the United States and any foreign country, it being understood that any expense incident to the execution of such papers shall be borne by the Assignee, its successors and assigns.

IN TESTIMONY WHEREOF, I have hereunto set my hand.

Charles Dauguet

2006-2-20
Date

JOINT INVENTION
Attorney Docket No. 03495.0010-20

ASSIGNMENT

WHEREAS I, the below named inventor, [hereinafter referred to as Assignor], have made an invention entitled:

DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

for which an application for United States Letters Patent was filed on September 19, 1994 (Application No. 08/308,219); and

WHEREAS, Institut Pasteur, whose post office address is 28, rue du Docteur Roux, 75724 Paris Cedex 15, France (hereinafter referred to as Assignee), is desirous of securing the entire right, title, and interest in and to this invention in the United States, and in and to the application for United States Letters Patent on this invention and the Letters Patent to be issued upon this application;

NOW THEREFORE, be it known that for good and valuable consideration the receipt of which from Assignee is hereby acknowledged, I, as Assignor, have sold, assigned, transferred, and set over, and do hereby sell, assign, transfer, and set over unto the Assignee, its lawful successors and assigns, my entire right, title, and interest in and to this invention, and this application, and all divisions, and continuations thereof, and all Letters Patent of the United States, which may be granted thereon, and all reissues thereof, and I hereby authorize and request the Commissioner of Patents and Trademarks of the United States, whose duty it is to issue patents on applications as described above, to issue all Letters Patent for this invention to Assignee, its successors and assigns, in accordance with the terms of this Assignment;

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IN TESTIMONY WHEREOF, I have hereunto set my hand.

Willy Rozenbaum

25 May 2006
Date

JOINT INVENTION
Attorney Docket No. 03495.0010-20

ASSIGNMENT

WHEREAS I, the below named inventor, [hereinafter referred to as Assignor], have made an invention entitled:

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IN TESTIMONY WHEREOF, I have hereunto set my hand.

Christine Rouzioux

30 05 2006
Date

JOINT INVENTION
Attorney Docket No. 03495.0010-20

ASSIGNMENT

WHEREAS I, the below named inventor, [hereinafter referred to as Assignor], have made an invention entitled:

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IN TESTIMONY WHEREOF, I have hereunto set my hand.

FRANÇOISE BRUN-VEZINET — 30/05/06

François Brun-Vezinet — Date

JOINT INVENTION
Attorney Docket No. 03495.0010-20

ASSIGNMENT

WHEREAS I, the below named inventor, [hereinafter referred to as Assignor], have made an invention entitled:

DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

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IN TESTIMONY WHEREOF, I have hereunto set my hand.

Luc Montagnier

May 24 2006
Date

JOINT INVENTION
Attorney Docket No. 03495.0010-20

ASSIGNMENT

WHEREAS I, the below named inventor, [hereinafter referred to as Assignor], have made an invention entitled:

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IN TESTIMONY WHEREOF, I have hereunto set my hand.

Jean Claude Chermann
Jean-Claude Chermann

May 26 06
Date

JOINT INVENTION
Attorney Docket No. 03495.0010-20

ASSIGNMENT

WHEREAS I, the below named inventor, [hereinafter referred to as Assignor], have made an invention entitled:

DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

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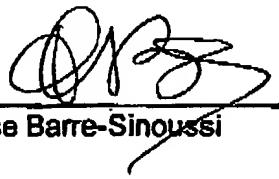

Françoise Barre-Sinoussi

05.24.2006
Date

JOINT INVENTION
Attorney Docket No. 03495.0010-20

ASSIGNMENT

WHEREAS I, the below named inventor, [hereinafter referred to as Assignor], have made an invention entitled:

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IN TESTIMONY WHEREOF, I have hereunto set my hand.

Pierre Tiollais

24 mai 06
Date

PATENT
Customer No. 22,852
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marc Alizon et al.

Application No.: 08/308,219

Filed: September 19,1994

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

Group Art Unit: 1637

Examiner: Jeffrey N. Fredman

Confirmation No.: 4832

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SUBMISSION UNDER 37 C.F.R. § 3.73(b)

The United States of America as represented by the Secretary of the Department of Heath and Human Services, having its principal place of business at 900 Rockville Pike, Bethesda, Maryland 20892, submits that it, together with Institut Pasteur of Paris, France, are the Assignees and owners of 100% of the right, title, and interest in the patent application identified above. The United States of America as represented by the Secretary of the Department of Heath and Human Services' ownership interest is evidenced by:

Assignments from Robert C. Gallo, Mikulas Popovic, and Mangalasseril G. Sarngadharan, who are being added as inventors to the patent application identified above; copies of these Assignments are included in Exhibit A attached hereto.

The undersigned is authorized to act on behalf of the assignee, The United States of America as represented by the Secretary of the Department of Heath and Human Services.

I hereby declare that all statements made of my own knowledge and belief are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

By: Jack Spiegel
Name: JACK SPIEGEL (REG# 34,477)
Title: SENIOR ADVISOR FOR TECHNOLOGY TRANSFER OPERATIONS
Assignee: The United States of America
as represented by the
Secretary of the Department of
Health and Human Services.

Dated: JUNE 5, 2006

1111556

ASSIGNMENT

WHEREAS I, the below named inventor, [hereinafter referred to as Assignor], have made an invention entitled:

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IN TESTIMONY WHEREOF, I have hereunto set my hand.

Robert C. Gallo — Robert C. Gallo

May 31, 06 — Date

ASSIGNMENT

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IN TESTIMONY WHEREOF, I have hereunto set my hand.

Mikulas Popovic

June 1, 2006
Date

ASSIGNMENT

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IN TESTIMONY WHEREOF, I have hereunto set my hand.

Mangalasseril G. Sarngadharan — June 4, 2006

Mangalasseril G. Sarngadharan — Date

Cloned DNA sequences related to the genomic RNA of lymphadenopathy-associated-virus (LAV) and proteins encoded by said LAV genomic RNA

The invention relates to cloned DNA sequences indistinguishable from genomic RNA and DNA of lymphadenopathy-associated virus (LAV), a process for their preparation and their uses. It relates more particularly to stable probes including a DNA sequence which can be used for the detection of the LAV virus or related viruses or DNA proviruses in any medium, particularly biological samples containing any of them. The invention also relates to polypeptides, whether glycosylated or not, encoded by said DNA sequences.

Lymphadenopathy-associated virus (LAV) is a human retrovirus first isolated from the lymph node of a homosexual patient with lymphadenopathy syndrome, frequently a prodrome or a benign form of acquired immune deficiency syndrome (AIDS). Subsequently other LAV isolates have been recovered from patients with AIDS or pre-AIDS. All available data are consistent with the virus being the causative agent of AIDS.

A method for cloning such DNA sequences has already been disclosed in British Patent Application Nr. 84 23659 filed on September 19, 1984. Reference is hereafter made to that application as concerns subject matter in common with the further improvements to the invention disclosed herein.

The present invention aims at providing additional new means which should not only also be useful for the detection of LAV or related viruses (hereafter more generally referred to as "LAV viruses"), but also have more versatility, particularly in detecting specific parts of the genomic DNA of said viruses whose expression products are not always directly detectable by immunological methods.

The present invention further aims at providing

polypeptides containing sequences in common with polypeptides encoded by the LAV genomic RNA. It relates even more particularly to polypeptides comprising antigenic determinants included in the proteins encoded and expressed by the LAV genome occuring in nature. An additional object of the invention is to further provide means for the detection of proteins related to LAV virus, particularly for the diagnosis of AIDS or pre-AIDS or, to the contrary, for the detection of antibodies against the LAV virus or proteins related therewith, particularly in patients afflicted with AIDS or pre-AIDS or more generally in asymtomatic carriers and in blood-related products. Finally the invention also aims at providing immunogenic polypeptides, and more particularly protective polypeptides for use in the preparation of vaccine compositions against AIDS or related syndroms.

The present invention relates to additional DNA fragments, hybridizable with the genomic RNA of LAV as they will be disclosed hereafter, as well as with additional cDNA variants corresponding to the whole genomes of LAV viruses. It further relates to DNA recombinants containing said DNAs or cDNA fragments.

The invention relates more particularly to a cDNA variant corresponding to the whole of LAV retroviral genomes, which is characterized by a series of restriction sites in the order hereafter (from the 5' end to the 3' end).

The coordinates of the successive sites of the whole LAV genome (restriction map) are indicated hereafter too, with respect to the Hind III site (selected as of coordinate 1) which is located in the R region. The coordinates are estimated with an accuracy of ± 200 bp :

Hind III	0
Sac I	50
Hind III	520
Pst I	800
Hind III	1 100

Bgl II	1 500
Kpn I	3 500
Kpn I	3 900
Eco RI	4 100
Eco RI	5 300
Sal I	5 500
Kpn I	6 100
Bgl II	6 500
Bgl II	7 600
Hind III	7 850
Bam HI	8 150
Xho I	8 600
Kpn I	8 700
Bgl II	8 750
Bgl II	9 150
Sac I	9 200
Hind III	9 250

Another DNA variant according to this invention optionally contains an additional Hind III approximately at the 5 550 coordinate.

Reference is further made to fig. 1 which shows a more detailed restriction map of said whole-DNA (λJ19).

An even more detailed nucleotidie sequence of a preferred DNA according to the invention is shown in fig. 4-12 hereafter.

The invention further relates to other preferred DNA fragments which will be referred to hereafter.

Additional features of the invention will appear in the course of the non-limitative disclosure of additional features of preferred DNAs of the invention, as well as of preferred polypeptides according to the invention. Reference will further be had to the drawings in which :

- fig. 1 is the restriction map of a complete LAV genome (clone λJ19) ;
- figs. 2 and 3 show diagrammatically parts of the three

possible reading phases of LAV genomic RNA, including the open reading frames (ORF) apparent in each of said reading phases :

- figs. 4-12 show the successive nucleotidic sequences of a complete LAV genome. The possible peptidie sequences in relation to the three possible reading phases related to the nucleotidie sequences shown are also indicated ;
- figs. 13-18 reiterate the sequence of part of the LAV genome containing the genes coding for the enveloppe proteins, with particular boxed peptidic sequences which corresponds to groups which normally carry glycosyl groups.

The sequencing and determination of sites of particular interest was carried out on a phage recombinant corresponding to λJ19 disclosed in the abovesaid British Patent application Nr. 84 23659. A method for preparing it is disclosed in that application.

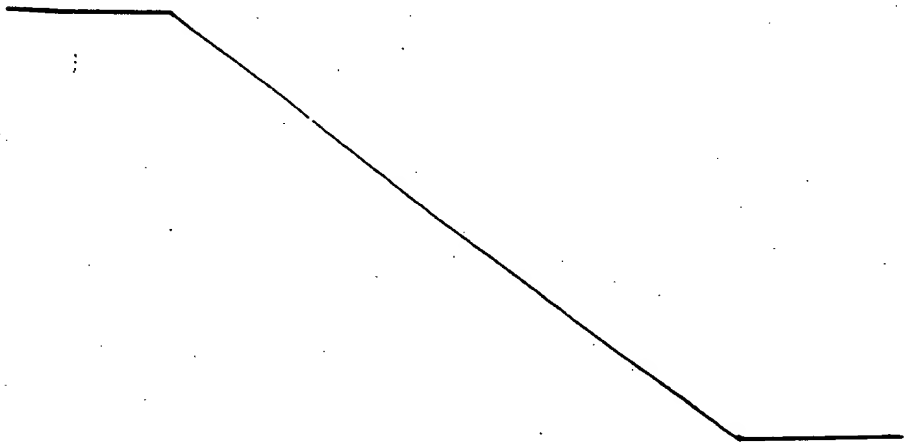
The whole recombinant phage DNA of clone λJ19 (disclosed in the earlier application) was sonicated according to the protocol of DEININGER (1983), Analytical Biochem. 129, 216. the DNA was repaired by a Klenow reaction for 12 hours at 16°C. The DNA was electrophoresed through 0.8 % agarose gel and DNA in the size range of 300-600 bp was cut out and electroeluted and precipitated. Resuspended DNA (in 10 mM Tris, pH 8 ; 0,1 mM EDTA) was ligated into M13mp8 RF DNA (cut by the restriction enzyme SmaI and subsequently alkaline phosphated), using T4 DNA- and RNA-ligases (Maniatis T et al (1982) - Molecular cloning - Cold Spring Harbor Laboratory). An E. coli strain designated as TG1 was used for further study. This strain has the following genotype :

Δlac pro, supE, thi.F'traD36, proAB, $lacI^q$, ZΔM15, r^-

This E. coli TGI strain has the peculiarity of enabling recombinants to be recognized easily. The blue colour of the cells transfected with plasmids which did

not recombine with a fragment of LAV DNA is not modified. To the contrary cells transfected by a recombinant plasmid containing a LAV DNA fragment yield white colonies. The technique which was used is disclosed in Gene (1983), 26, 101.

This strain was transformed with the ligation mix using the Hanahan method (Hanahan D (1983) J. Mol. Biol. 166, 557). Cells were plated out on tryptone-agarose plate with IPTG and X-gal in soft agarose. White plaques were either picked and screened or screened directly in situ using nitrocellulose filters. Their DNAs were hybridized with nick-translated DNA inserts of pUC18 Hind III subclones of λJ19. this permitted the isolation of the plasmids or subclones of λ which are identified in the table hereafter. In relation to this table it should also be noted that the designation of each plasmid is followed by the deposition number of a cell culture of E. coli TGI containing the corresponding plasmid at the "Collection Nationale des Cultures de Micro-organismes" (C.N.C.M.) of the Pasteur Institute in Paris, France. A non-transformed TGI cell line was also deposited at the C.N.C.M. under Nr. I-364. All these deposits took place on November 15, 1984. The sizes of the corresponding inserts derived from the LAV genome have also been indicated.



TABLE

Essential features of the recombinant plasmids

- pJ19 - 1 plasmid	(I-365)	0.5 kb
Hind III - Sac I - Hind III		
- pJ19 - 17 plasmid	(I-367)	0.6 kb
Hind III - Pst 1 - Hind III		
- pJ19 - 6 plasmid	(I-366)	1.5 kb
Hind III (5')		
Bam HI		
Xho I		
Kpn I		
Bgl II		
Sac I (3')		
Hind III		
- pJ19-13 plasmid	(I-368)	6.7 kb
Hind III (5')		
Bgl II		
Kpn I		
Kpn I		
Eco RI		
Eco RI		
Sal I		
Kpn I		
Bgl II		
Bgl II		
Hind III (3')		

Positively hybridizing M13 phage plates were grown up for 5 hours and the single-stranded DNAs were extracted.

M13mp8 subclones of λJ19 DNAs were sequenced according to the dideoxy method and technology devised by Sanger et al (Sanger et al (1977), Proc. Natl. Acad. Sci. USA, 74, 5463 and M13 cloning and sequencing handbook, AMERSHAM (1983). the 17-mer oligonucleotide primer α-^{35}SdATP (400Ci/mmol, AMERSHAM), and 0.5X-5X buffer gradient gels (Biggen M.D. et al (1983, Proc. Natl. Acad. Sci. USA, 50, 3963) were used. Gels were read and put into the computer under the programs of Staden (Staden R. (1982), Nucl. Acids Res. 10, 4731). All the appropriate references and methods can be found in the AMERSHAM M13 cloning and sequencing handbook.

The complete sequence of λJ19 was deduced from the experiments as further disclosed hereafter.

Figs. 4-12 provide the DNA nucleotidie sequence of the complete genome of LAV. The numbering of the nucleotides starts from a left most Hind III restriction site (5'AAG..) of the restriction map. The numbering occurs in tens whereby the last zero number of each of the numbers occuring on the drawings is located just below the nucleotide corresponding to the nucleotides designated. I.e. the nucleotide at position 10 is T, the nucleotide at position 20 is C, etc..

Above each of the lines of the successive nucleotidic sequences there are provided three lines of single letters corresponding to the aminoacid sequence deduced from the DNA sequence (using the genetic code) for each at the three reading phases, whereby said single letters have the following meanings.

A : alanine
R : arginine
K : lysine
H : histidine
C : cysteine

M : méthionine
W : tryptophan
F : phenylalanine
Y : tyrosine
L : leucine
V : valine
I : isoleucine
G : glycine
T : thréonine
S : serine
E : glutamic acid
D : Aspartic acid
N : asparagine
Q : glutamine
P : proline.

The asterik signs "*" correspond to stop codons (i.e. TAA, TAG and TGA).

Starting above the first line of the DNA nucleotidic sequence of fig. 4 the three reading phases are respectively marked "1", "2", "3", on the left handside of the drawing. The same relative presentation of the three theoritical reading phases is then used all over the successives lines of the LAV nucleotidic sequence.

Figs. 2 and 3 provide a diagrammatized representation of the lengths of the successive open reading frames corresponding to the successive reading phases (also referred to by numbers "1", "2" and "3" appearing in the left handside part of fig. 2). The relative positions of these open reading frames (ORF) with respect to the nucleotidic structure of the LAV genome is referred to by the scale of numbers representative of the respective positions of the corresponding nucleotides in the DNA sequence. The vertical bars correspond to the positions of the corresponding stop codons.

1) <u>The "gag gene" (or ORF-gag)</u>

The "gag gene" codes for core proteins.

Particularly it appears that a genomic fragment (ORF-gag) thought to code for the core antigens including the p25, p18 and p13 proteins is located between nucleotidic position 236 (starting with 5' CTA GCG GAG 3') and nucleotidic position 1759 (ending by CTCG TCA CAA 3'). The structure of the peptides or proteins encoded by parts of said ORF is deemed to be that corresponding to phase 2.

The methionine aminoacid "M" coded by the ATG at position 260-262 is the probable initiation methionine of the gag protein precursor. The end of ORF-gag and accordingly of gag protein appears to be located at position 1759.

The beginning of p25 protein, thought to start by a P-I-V-Q-N-I-Q-G-Q-M-V-H .... aminoacid sequence is thought to be coded for by the nucleotidic sequence CCTATA..., starting at position 656.

Hydrophilic peptides in the gag open reading frame are identified hereafter. They are defined starting from aminoacid 1 = Met (M) coded by the ATG starting from 260-2 in the LAV DNA sequence.

Those hydrophilic peptides are

12-32	aminoacids	inclusive
37-46	"	"
49-79	"	"
88-153	"	"
158-165	"	"
178-188	"	"
200-220	"	"
226-234	"	"
239-264	"	"
288-331	"	"
352-361	"	"
377-390	"	"
399-432	"	"
437-484	"	"
492-498	"	"

The invention also relates to any combination of these peptides.

2) <u>The "pol gene" (or ORF-pol)</u>

Figs. 4-12 also show that the DNA fragments extending from nucleotidic position 1555 (starting with 5'TTT TTT ....3' to nucleotidic position 5086 is thought to correspond to the pol gene. The polypeptidic structure of the corresponding polypeptides is deemed to be that corresponding to phase 1. It stops at position 4563 (end by 5'G GAT GAG GAT 3').

These genes are thought to code for the virus polymerase or reverse transcriptase.

3) <u>The envelope gene (or ORF-env)</u>

The DNA sequence thought to code for envelope proteins is thought to extend from nucleotidic position 5670 (starting with 5'AAA GAG GAG A....3') up to nucleotidic position 8132 (ending by ....A ACT AAA GAA 3'). Polypeptidic structures of sequences of the envelope protein correspond to those read according to the "phase 3" reading phase.

The start of env transcription is thought to be at the level of th ATG codon at positions 5691-5693.

Additional feature of the envelope protein coded by the env genes appear on figs. 13-18. These are to be considered as paired figs. 13 and 14 ; 15 and 16 ; 17 and 18 respectively.

It is to be mentioned that because of format difficulties.

Fig. 14 overlaps to some extent with fig. 13.

Fig. 16 overlaps to some extent with fig. 15.

Fig. 18 overlaps to some extent with fig. 17.

Thus for instance figs. 13 and 14 must be considered together. Particularly the sequence shown on the first line on the top of fig. 13 overlaps with the sequence shown on the first line on the top of fig. 14. In other words the starting of the reading of the successive

sequences of the env gene as represented in figs. 13-18 involves first reading the first line at the top of fig. 13 then proceeding further with the first line of fig. 14. One then returns to the beginning of the second line of fig. 13, then again further proceed with the reading of the second line of page 14, etc... The same observations then apply to the reading of the paired figs. 15 and 16, and paired figs. 17 and 18, respectively.

The locations of neutralizing epitopes are further apparent in figs. 13-18. reference is more particularly made to the boxed groups of three letters included in the aminoacid sequences of the envelope proteins (reading phase 3) which can be designated generally by the formula N-X-S or N-X-T, wherein X is any other possible aminoacid. Thus the initial protein product of the env gene in a glycoprotein of molecular weight in excess of 91,000. These groups are deemed to generally carry glycosylated groups. These N-X-S and N-X-T groups with attached glycosylated groups form together hydrophylic regions of the protein and are deemed to be located at the periphery of and to be exposed outwardly with respect to the normal conformation of the proteins. Consequently they are considered as being epitopes which can efficiently be brought into play in vaccine compositions.

The invention thus concerns with more particularity peptide sequences included in the env-proteins and excizable therefrom (or having the same aminoacid structure), having sizes not exceeding 200 aminoacids.

Preferred peptides of this invention (referred to hereafter as a, b, c, d, e, f) are deemed to correspond to those encoded by the nucleotide sequences which extend respectively between the following positions :

a) from about 6095 to about 6200
b) " " 6260 " " 6310
c) " " 6390 " " 6440
d) " " 6485 " " 6620

e) " " 6860 " " 6930

f) " " 7535 " " 7630

Other hydrophilic peptides in the env open reading frame are identified hereafter. they are defined starting from

aminoacid 1 = lysine (K) coded by the AAA at position 5670-2 in the LAV DNA sequence.

These hydrophilic peptides are

8-23	aminoacids	inclusive
63-78	"	"
82-90	"	"
97-123	"	"
127-183	"	"
197-201	"	"
239-294	"	"
300-327	"	"
334-381	"	"
397-424	"	"
466-500	"	"
510-523	"	"
551-577	"	"
594-603	"	"
621-630	"	"
657-679	"	"
719-758	"	"
780-803	"	"

The invention also relates to any combination of these peptides.

4) <u>The other ORF</u>

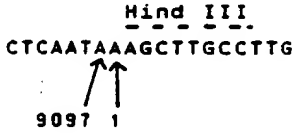
The invention further concerns DNA sequences which provide open reading frames defined as ORF-Q, ORF-R and as "1", "2", "3", "4", "5", the relative position of which appears more particularly in figs. 2 and 3.

These ORFs have the following locations :

ORF-Q	phase 1	start	4478	stop	5086
ORF-R	" 2	"	8249	"	8896

ORF-1	"	1	"	5029	" 5316
ORF-2	"	2	"	5273	" 5515
ORF-3	"	1	"	5383	" 5616
ORF-4	"	2	"	5519	" 5773
ORF-5	"	1	"	7966	" 8279

The LTR (long terminal repeats) can be defined as lying between position 8560 and position 160 (end extending over position 9097/1). As a matter of fact the end of the genome is at 9097 and, because of the LTR structure of the retrovirus, links up with the beginning of the sequence :



The invention concerns more particularly all the DNA fragments which have been more specifically referred to hereabove and which correspond to open reading frames. It will be understood that the man skilled in the art will be able to obtain them all, for instance by cleaving an entire DNA corresponding to the complete genome of a LAV species, such as by cleavage by a partial or complete digestion thereof with a suitable restriction enzyme and by the subsequent recovery of the relevant fragments. The different DNAs disclosed in the earlier mentioned British Application can be resorted to also as a source of suitable fragments. The techniques disclosed hereabove for the isolation of the fragments which were then included in the plasmids referred to hereabove and which were then used for the DNA sequencing can be used.

Of course other methods can be used. Some of them have been examplified in the earlier British Application. reference is for instance made to the following methods.

a) DNA can be transfected into mammalian cells with appropriate selection markers by a variety of techniques, calcium phosphate precipitation, polyethylene

glycol, protoplast-fusion, etc..

b) DNA fragments corresponding to genes can be cloned into expression vectors for E. coli , yeast- or mammalian cells and the resultant proteins purified.

c) The provival DNA can be "shot-gunned" (fragmented), into procaryotic expression vectors to generate fusion polypeptides. Recombinant producing antigenically competent fusion proteins can be identified by simply screening the recombinants with antibodies against LAV antigens .

The invention also relates more specifically to cloned probes which can be made starting from any DNA fragment according to this invention, thus to recombinant DNAs containing such fragments, particularly any plasmids amplifiable in procaryotic or eucaryotic cells and carrying said fragments.

Using the cloned DNA fragments as a molecular hybridization probe - either by marking with radionucleotides or with fluorescent reagents - LAV virion RNA may be detected directly in the blood, body fluids and blood products (e.g. of the antihemophylic factors such as Factor VIII concentrates) and vaccines, i.e. hepatitis B vaccine. It has already been shown that whole virus can be detected in culture supernatants of LAV producing cells. A suitable method for achieving that detection comprises immobilizing virus onto said a support e.g. nitrocellulose filters, etc., disrupting the virion and hybridizing with labelled (radiolabelled or "cold" fluorescent- or enzyme-labelled) probes. Such an approach has already been developed for Hepatitis B virus in peripheral blood (according to SCOTTO J. et al. Hepatology (1983), 3, 379-384).

Probes according to the invention can also be used for rapid screening of genomic DNA derived from the tissue of patients with LAV related symptoms, to see if the proviral DNA or RNA is present in host tissue and other

tissues.

A method which can be used for such screening comprise the following steps : extraction of DNA from tissue, restriction enzyme cleavage of said DNA, electrophoresis of the fragments and Southern blotting of genomic DNA from tissues, subsequent hybridization with labelled cloned LAV provival DNA. Hybridization in situ can also be used.

Lymphatic fluids and tissues and other non-lymphatic tissues of humans, primates and other mammalian species can also be screened to see if other evolutionnary related retrovirus exist. The methods referred to hereabove can be used, although hybridization and washings would be done under non stringent conditions.

The DNA according to the invention can be used also for achieving the expression of LAV viral antigens for diagnostic purposes.

The invention also relates to the polypeptides themselves which can be expressed by the different DNAs of the inventions, particularly by the ORFs or fragments thereof, in appropriate hosts, particularly procaryotic or eucaryotic hosts, after transformation thereof with a suitable vector previously modified by the corresponding DNAs.

These polypeptides can be used as diagnostic tools, particularly for the detection of antibodies in biological media, particularly in sera or tissues of persons afflicted with pre-AIDS or AIDS, or simply carrying antibodies in the absence of any apparent disorders. Conversely the different peptides according to this invention can be used themselves for the production of antibodies, preferably monoclonal antibodies specific of the different peptides respectively. For the production of hybridomas secreting said monoclonal antibodies conventional production and screening methods are used. These monoclonal antibodies, which themselves are part of

the invention than provide very useful tools for the identification and even determination of relative proportions of the different polypeptides or proteins in biological samples, particularly human samples containing LAV or related viruses.

Thus all of the above peptides can be used in diagnostics as sources of immunogens or antigens free of viral particles, produced using non-permissive systems, and thus of little or no biohazard risk.

The invention further relates to the hosts (procaryotic or eucaryotic cells) which are transformed by the above mentioned recombinants and which are capable of expressing said DNA fragments.

Finally it also relates to vaccine compositions whose active principle is to be constituted by any of the expressed antigens, i.e. whole antigens, fusion polypeptides or oligopeptides in association with a suitable pharmaceutical or physiologically acceptable carrier.

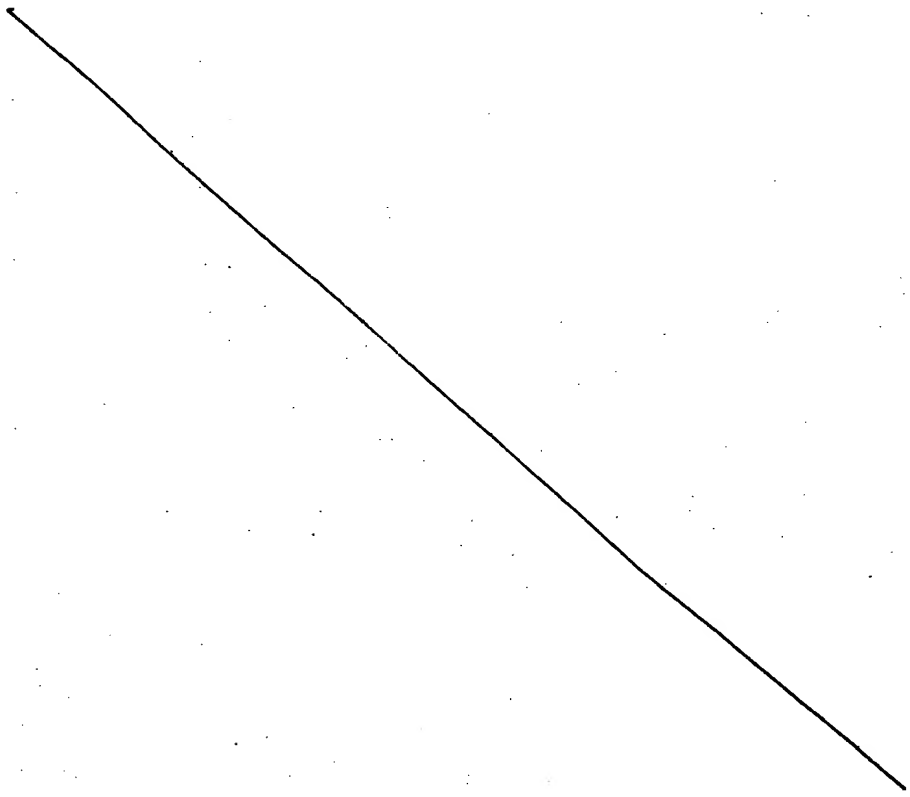
Preferably the active principles to be considered in that field consist of the peptides containing less than 250 aminoacid units, preferably less than 150 as deducible for the complete genomas of LAV, and even more preferably those peptides which contain one or more groups selected from N-X-S and N-X-T as defined above. Preferred peptides for use in the production of vaccinating principles are peptides (a) to (f) as defined above. By way of example having no limitative character, there may be mentioned that suitable dosages of the vaccine compositions are those which enable administration to the host, particularly human host ranging from 10 to 500 micrograms per kg, for instance 50 to 100 micrograms per kg.

For the purpose of clarity figs. 19 to 26 are added, reference may be made thereto in case of difficulties of reading blurred parts of figs. 4 to 12.

Needless to say that figs. 19-26 are merely a reiteration of the whole DNA sequence of the LAV genoma.

Finally the invention also concerns vectors for the transformation of eucaryotic cells of human origin, particularly lymphocytes, the polymerases of which are capable of recognizing the LTRs of LAV. Particularly said vectors are characterized by the presence of a LAV LTR therein, said LTR being then active as a promoter enabling the efficient transcription and translation in a suitable host of the above defined, of a DNA insert coding for a determined protein placed under its controls.

Needless to say that the invention extends to all variants of genomes and corresponding DNA fragments (ORFs) having substantially equivalent properties, all of said genomes belonging to retroviruses which can be considered as equivalents of LAV.



CLAIMS

1. A DNA fragment of LAV extending from nucleotide position 236 to nucleotide position 1759.

2. A DNA fragment of LAV extending from nucleotide position 1555 to nucleotide position 5086.

3. A DNA fragment of LAV extending from nucleotide position 5670 to nucleotide position 8132.

4. A vector containing a DNA fragment according to any of claims 1 to 3.

5. Peptide corresponding to any of those encoded by the nucleotide sequences which extend respectively between the following positions :

a) from about 6095 to about 6200
b) " " 6260 " " 6310
c) " " 6390 " " 6440
d) " " 6485 " " 6620
e) " " 6860 " " 6930
f) " " 7535 " " 7630

6. Peptide characterized by a sequence of amino-acids deducible from LAV DNA the terminal aminoacids of which extend between the following positions with respect to the lysine (position 1) coded by the AAA at position 5670-5672 in the LAV DNA.

8-23 aminoacids inclusive
63-78 " "
82-90 " "
97-123 " "
127-183 " "
197-201 " "
239-294 " "
300-327 " "
334-381 " "
397-424 " "
466-500 " "
510-523 " "
551-577 " "

594-603 " "
621-630 " "
657-679 " "
719-758 " "
780-803 " "

or any combination of these peptides.

7. Peptide corresponding to the aminoacid sequences deducible from LAV DNA and the terminal aminoacids of which are positionned at the positions hereafter counted from the Met at position 1 coded by the ATG sequence at nucleotide positions 260-2 :

12-32 aminoacids inclusive
37-46 " "
49-79 " "
88-153 " "
158-165 " "
178-188 " "
200-220 " "
226-234 " "
239-264 " "
288-331 " "
352-361 " "
377-390 " "
399-432 " "
437-484 " "
492-498 " "

and combination of said peptides.

8. Diagnostic means containing any of the DNA fragments of any of claims 1 to 3.

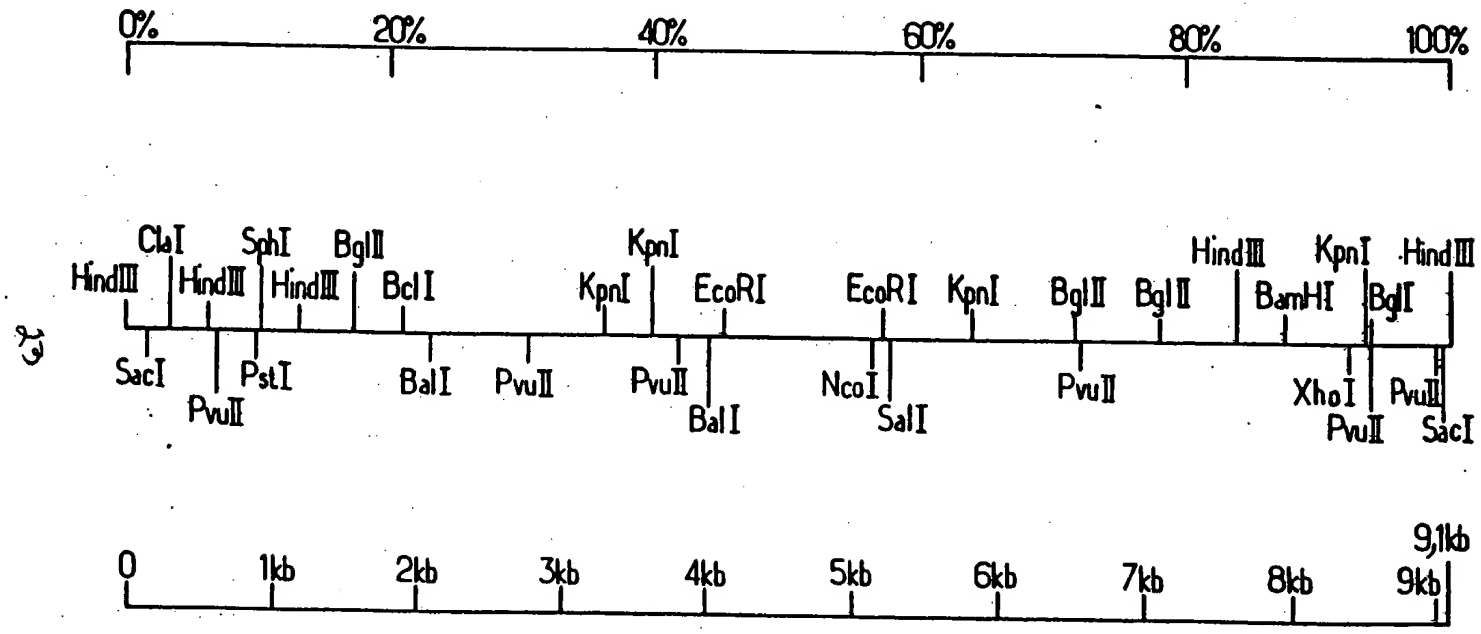
9. Diagnostic means containing any of the peptides of any of claims 4 to 6.

10. Vaccine compositions containing any of the peptides according to any of claims 4 to 6 in association with a pharmaceutical vehicle.

ABSTRACT

This invention is in the field of lymphadenopathy virus. This invention relates to a diagnostic means and method to detect the presence of DNA, RNA or antibodies of the lymphadenopathy retrovirus associated with the acquired immune deficiency syndrome or of the lymphadenopathy syndrome by the use of DNA fragments or the peptides encoded by said DNA fragments. The invention further relates to the DNA fragments, vectors comprising them and the proteins expressed.

FIG.1.


0%
20%
40%
60%
80%
100%
ClaI
SphI
BglII
KpnI
HindIII
HindIII
HindIII
HindIII
BclI
KpnI
EcoRI
EcoRI
KpnI
BglII
BglII
HindIII
KpnI
HindIII
BamHI
BglI
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PvuII
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BalI
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NcoI
SalI
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XhoI
PvuII
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8kb
9kb
9,1kb

Fig. 2.

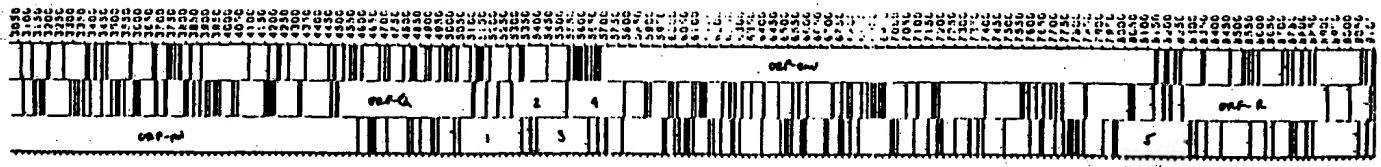

Fig. 3

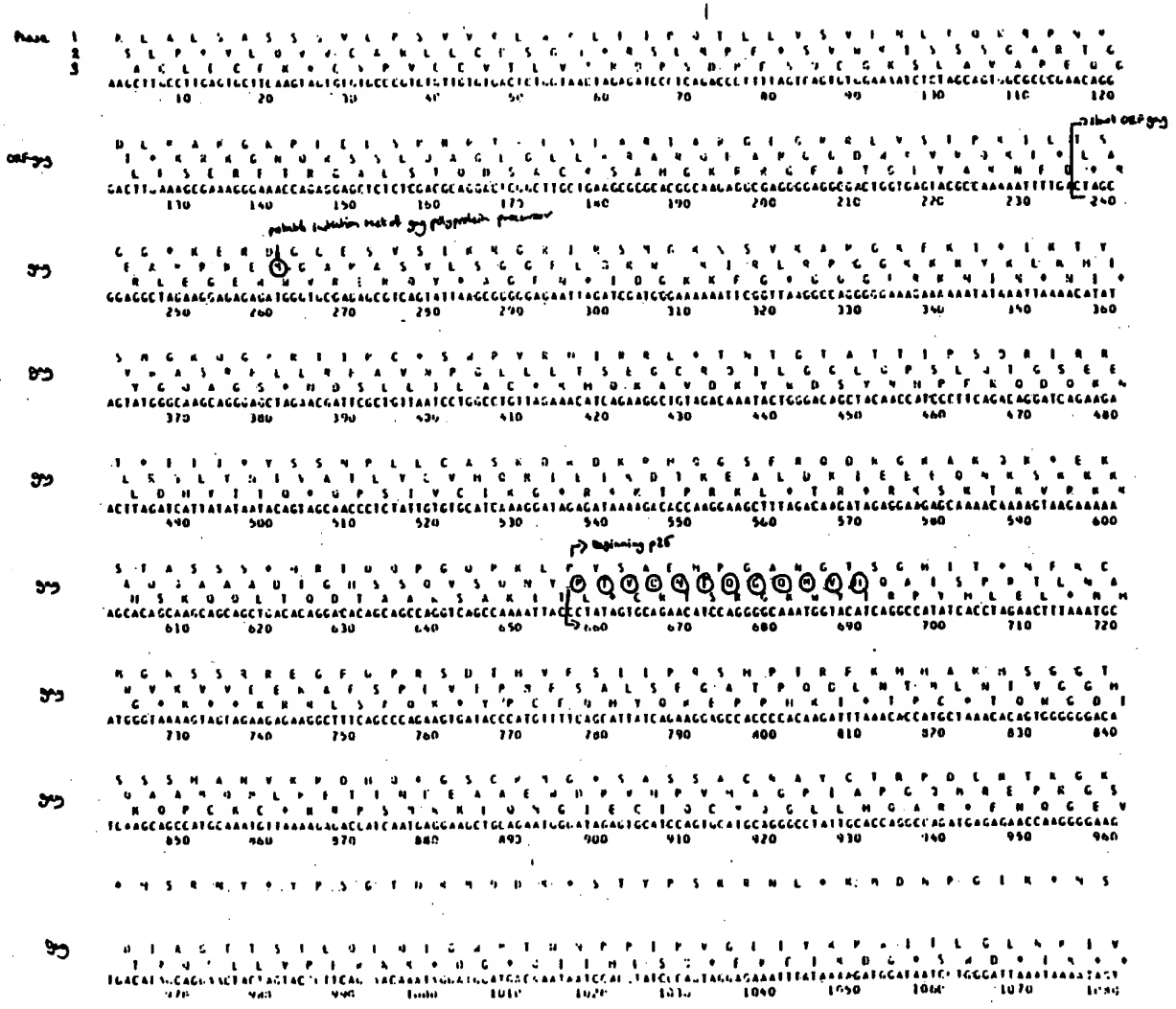

Fig 4

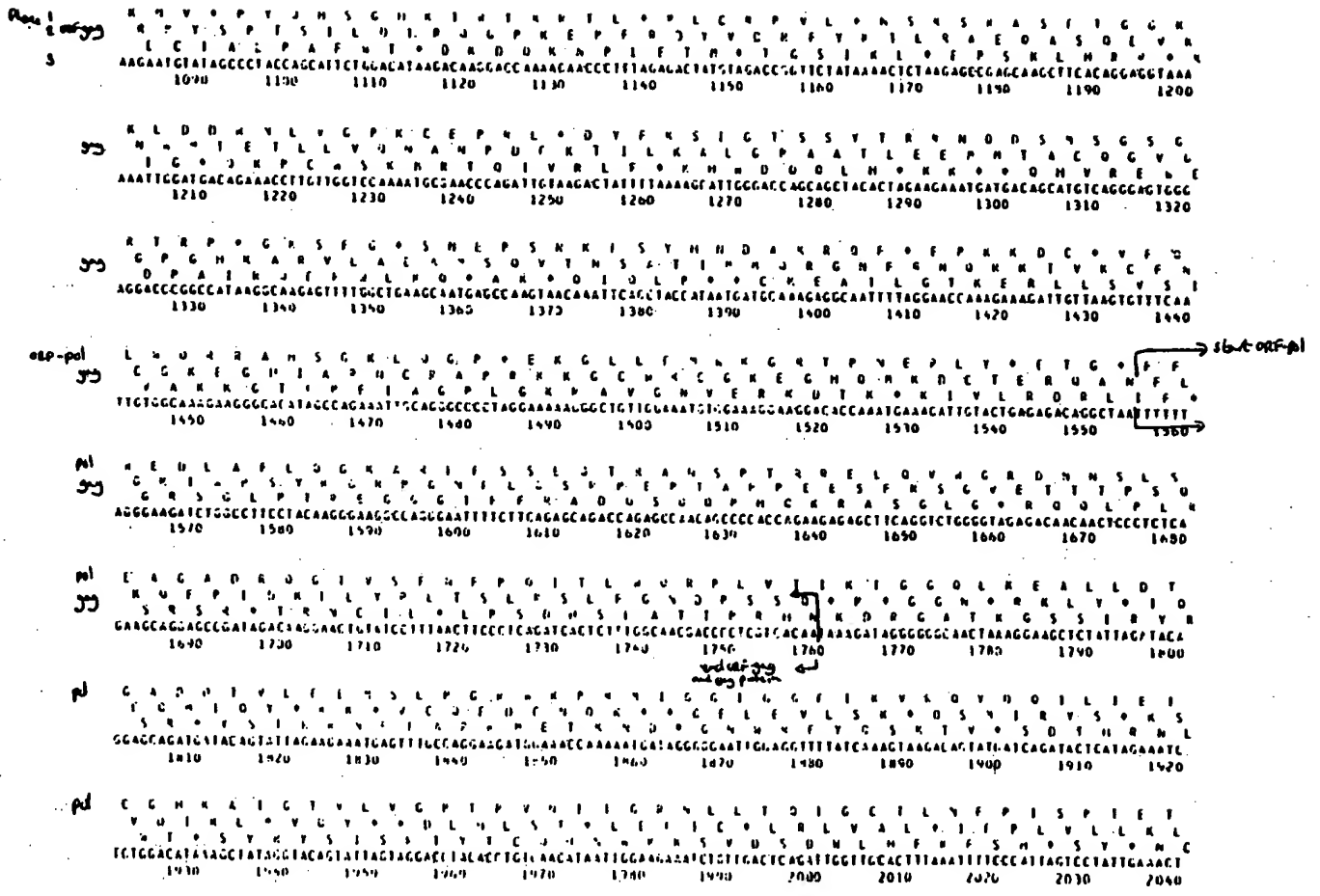

Fig. 5

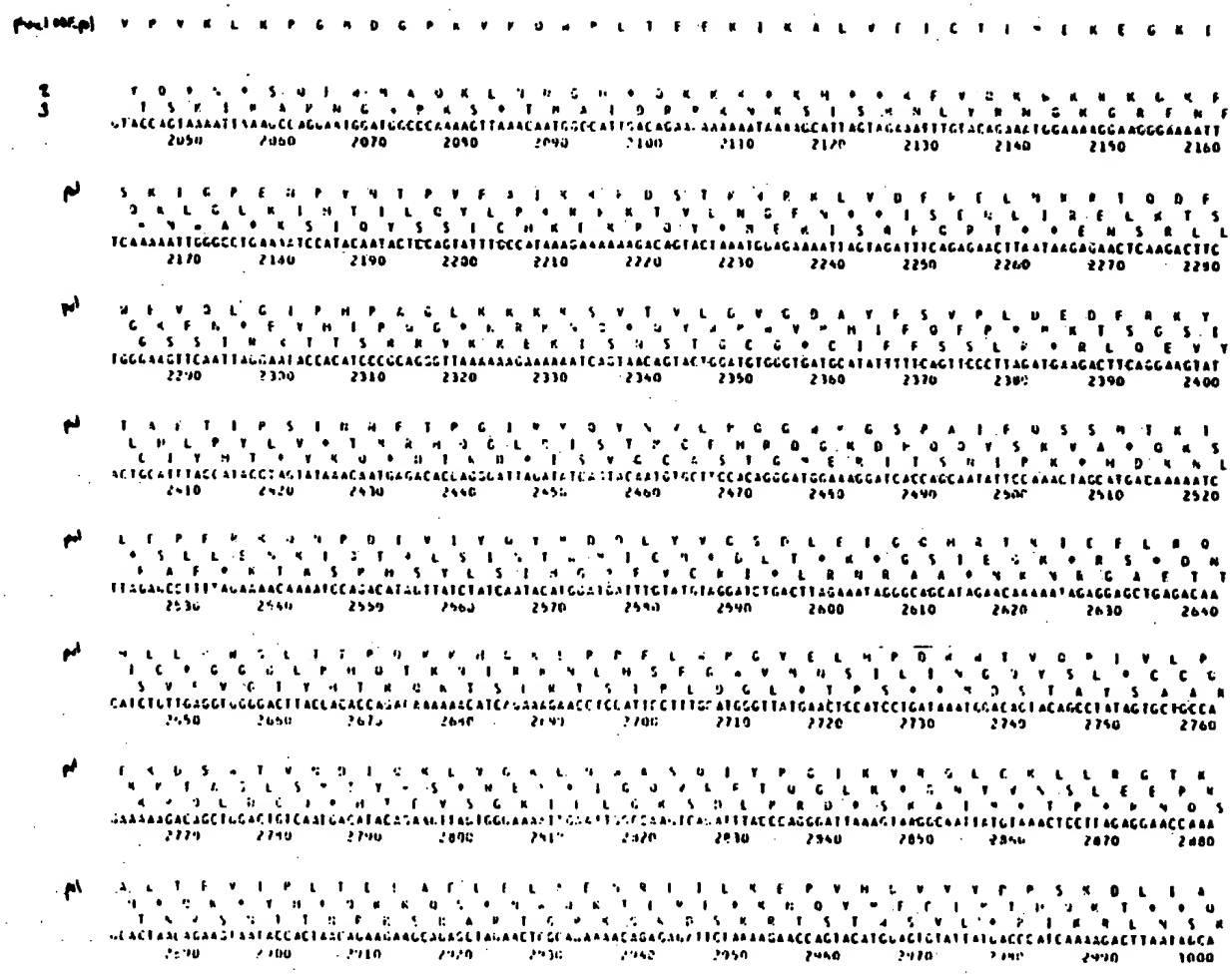

Fig 6

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Mael ... pol

GAAATACAGAAGCAGGGGCAAGGCCAATGGACATATCAAATTTATCAAGAGCCATTTAAAAATTCTGAAAACAGGAAAAATATGCCAAGAACGAGGGTTGCCCACACTAATGATGTAAAACAA

3010 3020 3030 3040 3050 3060 3070 3080 3090 3100 3110 3120

TTAACAGAGGCAGTGCAAAAAATAACCACAGAAAGCATAGTAATATGGGGAGAACTCCTAAATTTAAACTACCCATACAAAAGGAAACATGGGAAACATGGTGGACAGAGTATTGGCAA

3130 3140 3150 3160 3170 3180 3190 3200 3210 3220 3230 3240

GCCACCTGGATTCCTGAGTGGGAGTTTGTCAATACTCCTCCTTTAGTCAAATTATGGTACCAGTTAGAGAAAGAACCCATAGTAGGAGCAGAAACGTTCTATGTAGATGGGGCAGCTAGC

3250 3260 3270 3280 3290 3300 3310 3320 3330 3340 3350 3360

AGGGAGACTAAATTAGGAAAAGCAGGATATGTTACTAATAGAGGAAGACAAAAAGTTGTCACCCTAACTGACACAACAAATCAGAAGACTGAGTTACAAGCAATTCATCTAGCTTTGCAG

3370 3380 3390 3400 3410 3420 3430 3440 3450 3460 3470 3480

GATTCGGGATTAGAAGTAAATATAGTAACAGACTCACAATATGCATTAGGAATCATTCAAGCACAACCAGATAAAAGTGAATCAGAGTTAGTCAATCAAATAATAGAGCAGTTAATAAAA

3490 3500 3510 3520 3530 3540 3550 3560 3570 3580 3590 3600

AAGGAAAAGGTCTATCTGGCATGGGTACCAGCACACAAAGGAATTGGAGGAAATGAACAAGTAGATAAATTAGTCAGTGCTGGAATCAGGAAAGTACTATTTTTAGATGGAATAGATAAG

3610 3620 3630 3640 3650 3660 3670 3680 3690 3700 3710 3720

GCCCAAGATGAACATGAGAAATATCACAGTAATTGGAGAGCAATGGCTAGTGATTTTAACCTGCCACCTGTAGTAGCAAAAGAAATAGTAGCCAGCTGTGATAAATGTCAGCTAAAAGGA

3730 3740 3750 3760 3770 3780 3790 3800 3810 3820 3830 3840

GAAGCCATGCATGGACAAGTAGACTGTAGTCCAGGAATATGGCAACTAGATTGTACACATTTAGAAGGAAAAGTTATCCTGGTAGCAGTTCATGTAGCCAGTGGATATATAGAAGCAGAA

3850 3860 3870 3880 3890 3900 3910 3920 3930 3940 3950 3960

GTTATTCCAGCAGAAACAGGGCAGGAAACAGCATATTTTCTTTTAAAATTAGCAGGAAGATGGCCAGTAAAAACAATACATACAGACAATGGCCAGCAATTTCACCAGTACTACGGTTAAG

3970 3980 3990 4000 4010 4020 4030 4040 4050 4060 4070 4080

Fig 7

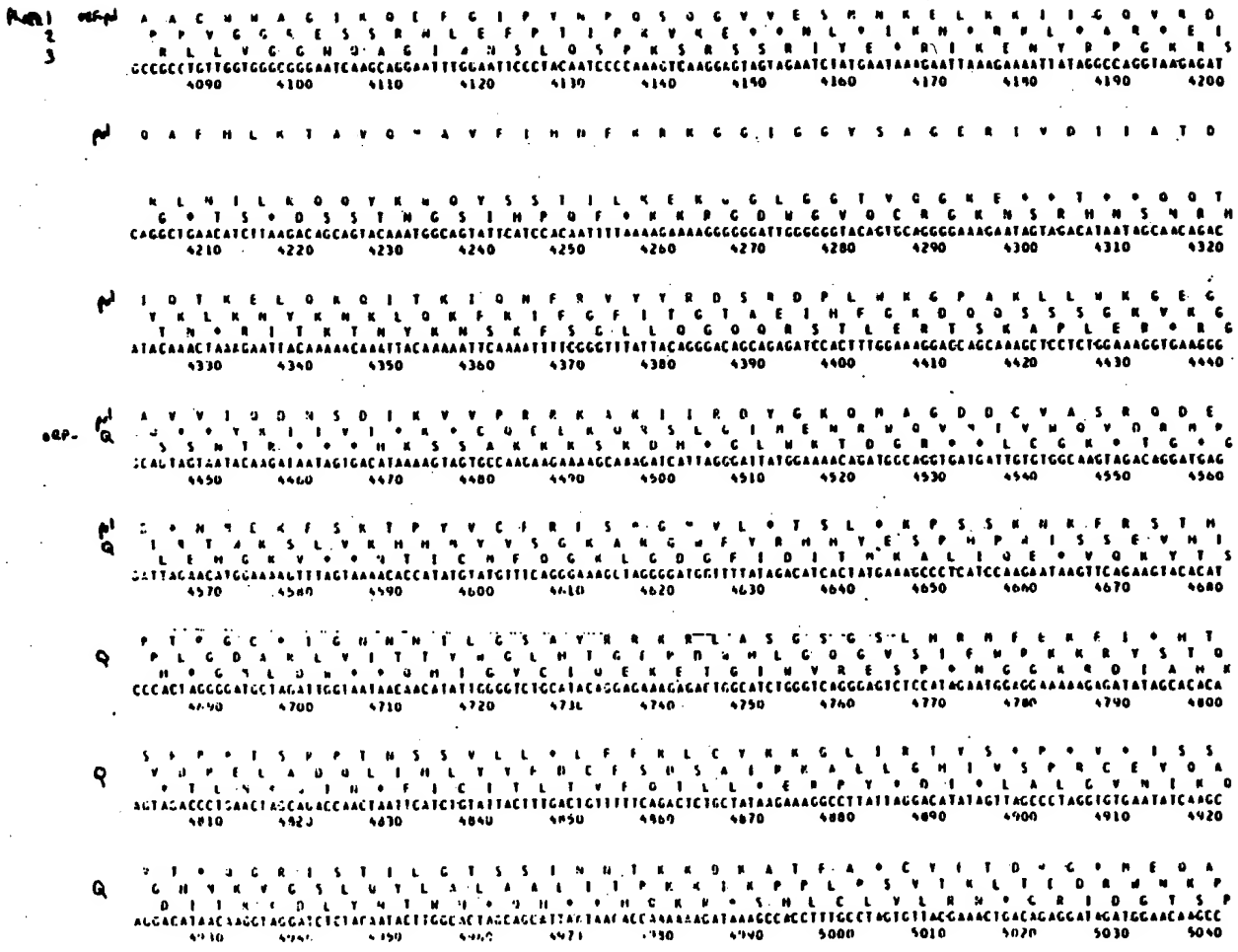


Fig. 8

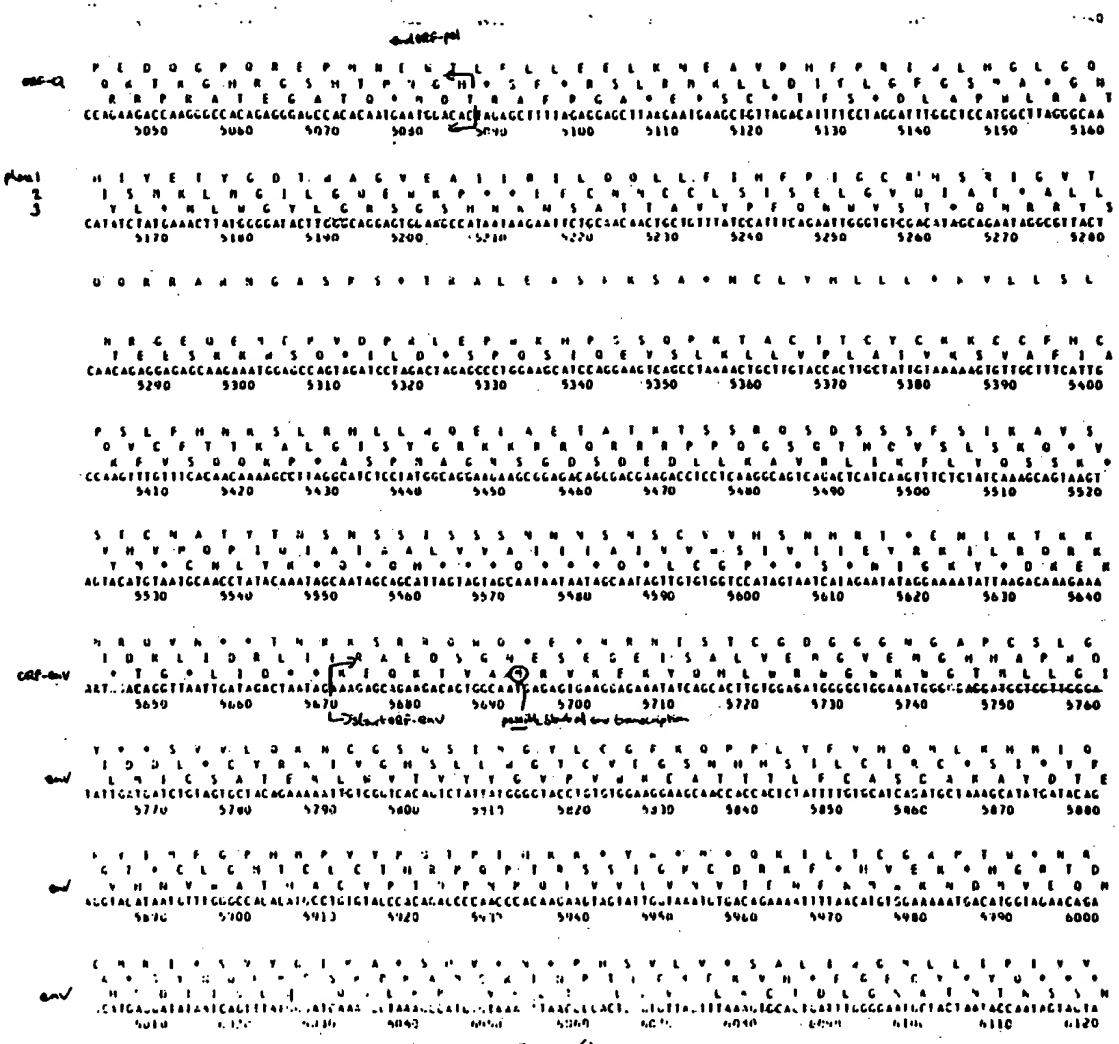


Fig 9

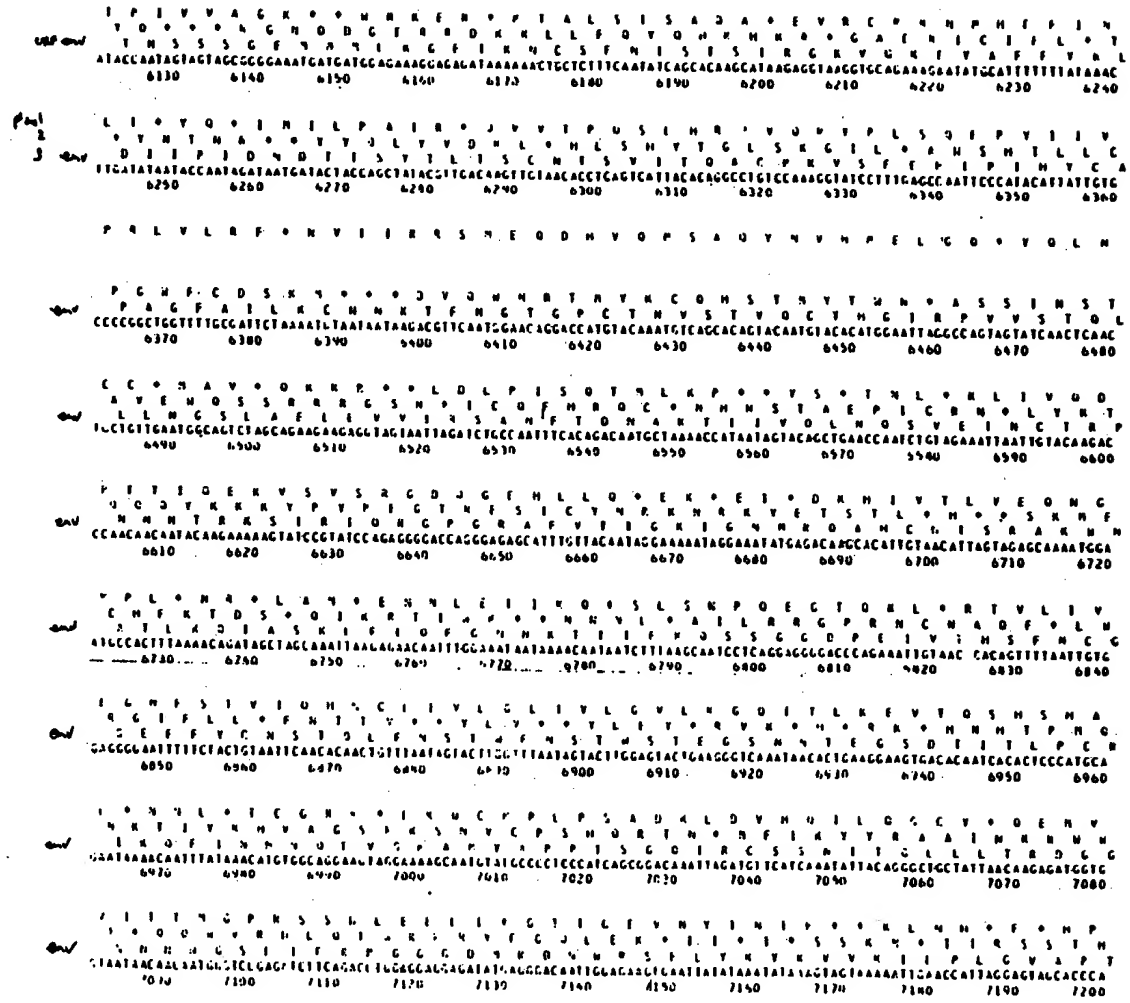
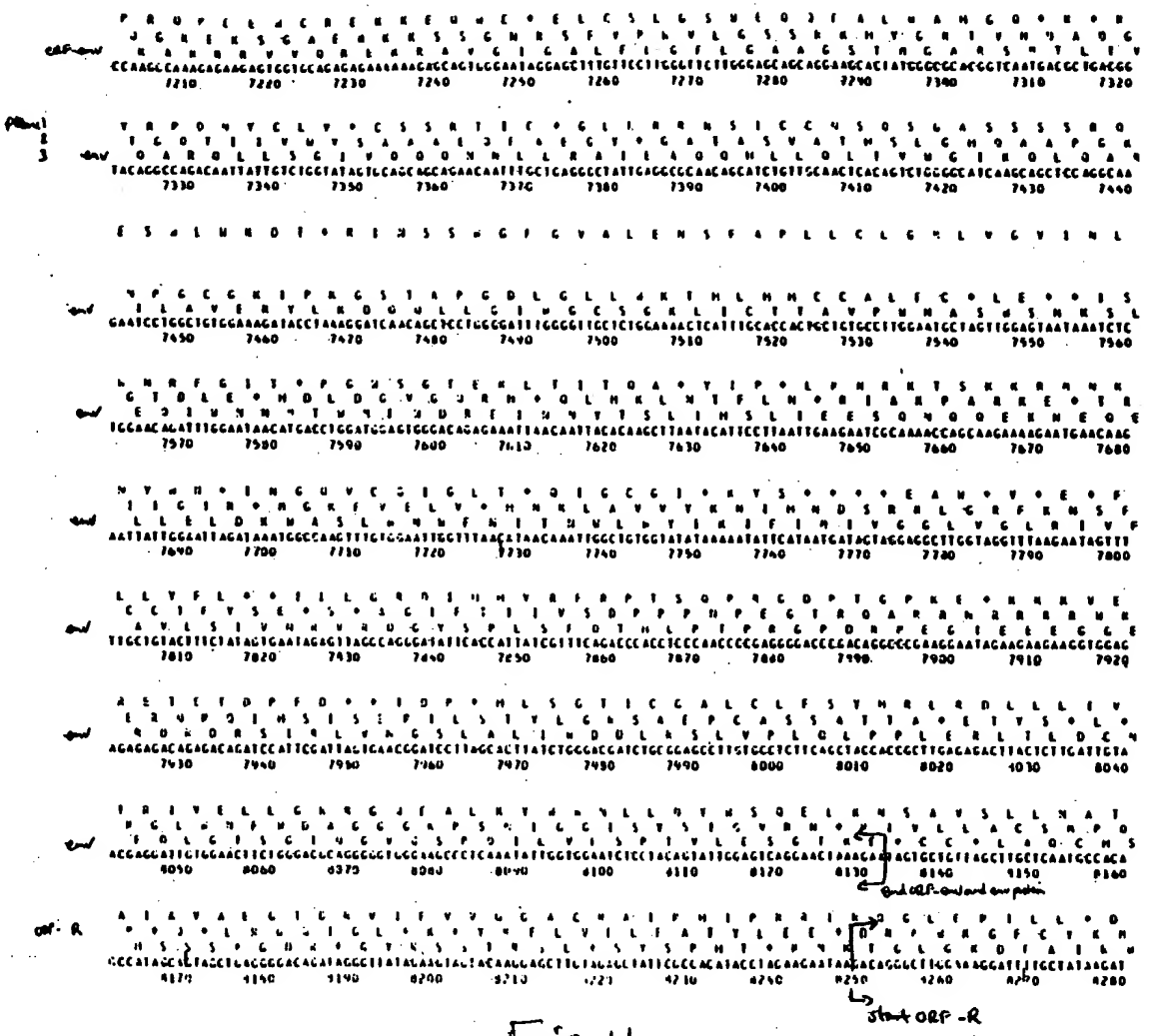


Fig 10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7570 7580 7590 7600 7610 7620 7630 7640 7650 7660 7670 7680
7690 7700 7710 7720 7730 7740 7750 7760 7770 7780 7790 7800
7810 7820 7830 7840 7850 7860 7870 7880 7890 7900 7910 7920
7930 7940 7950 7960 7970 7980 7990 8000 8010 8020 8030 8040
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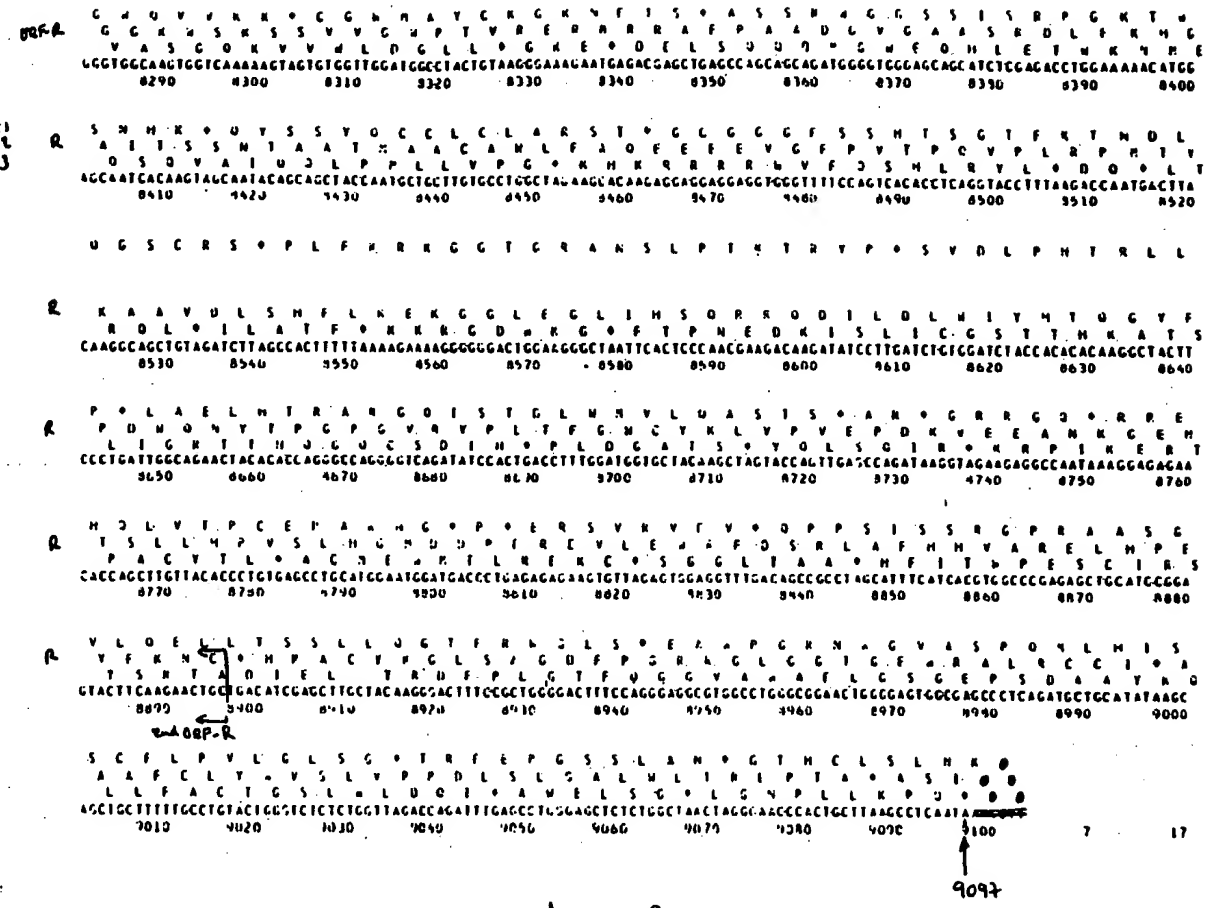
start ORF-R

Fig 11


ORF-R
R
R
R
R
R
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8650 8660 8670 8680 8690 8700 8710 8720 8730 8740 8750 8760
8770 8780 8790 8800 8810 8820 8830 8840 8850 8860 8870 8880
8890 8900 8910 8920 8930 8940 8950 8960 8970 8980 8990 9000
ORF-R
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9097

fig 12

771248

Fig 13

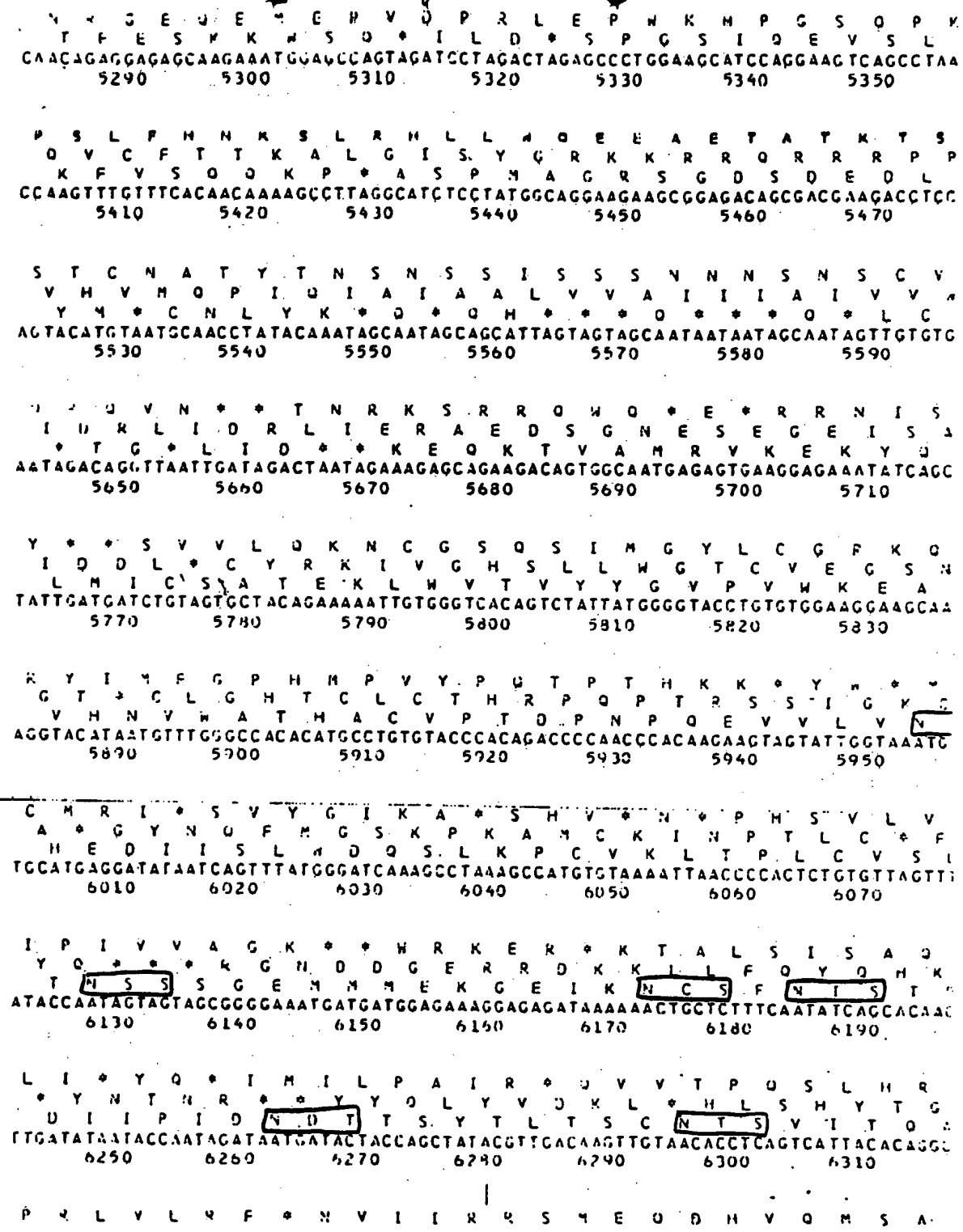

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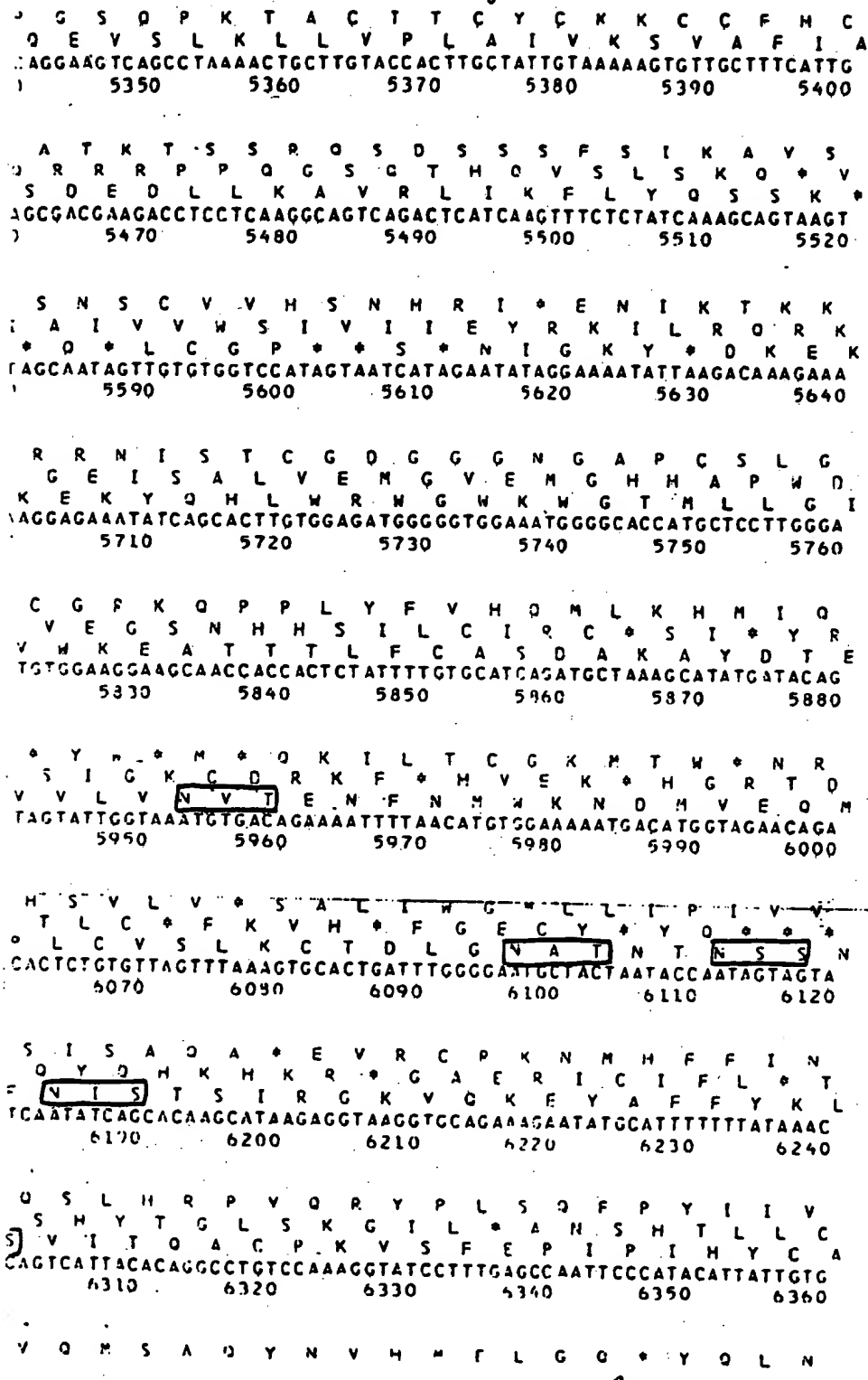
Fig 14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5470 5480 5490 5500 5510 5520
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5590 5600 5610 5620 5630 5640
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5710 5720 5730 5740 5750 5760
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5830 5840 5850 5860 5870 5880
TAGTATTGGTAAATGTGACAGAAAATTTTAACATGTGGAAAAATGACATGGTAGAACAGA
5950 5960 5970 5980 5990 6000
CACTCTGTGTTAGTTTAAAGTGCACTGATTTGGGGAATGCTACTAATACCAATAGTAGTA
6070 6080 6090 6100 6110 6120
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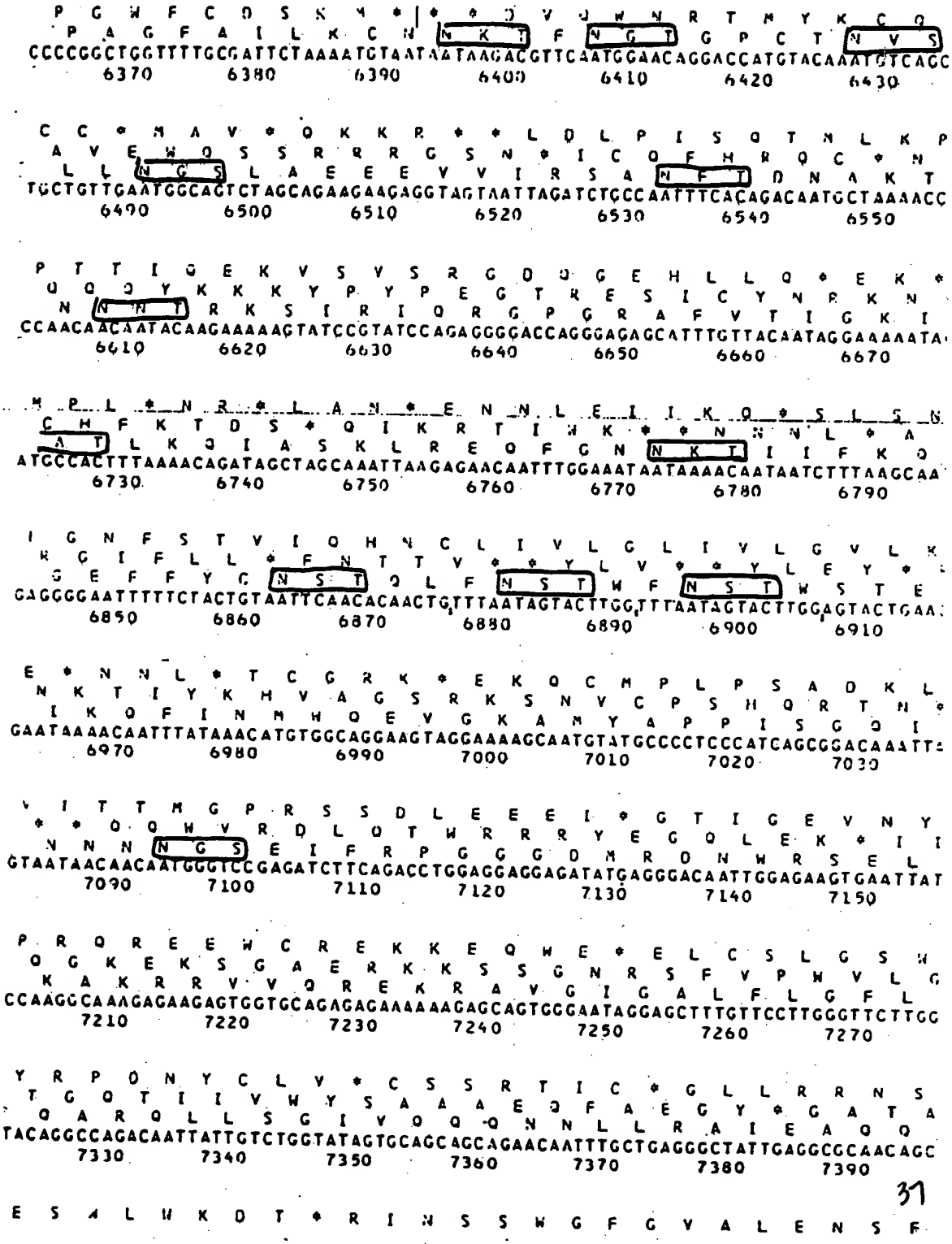
360

Fig 15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6850 6860 6870 6880 6890 6900 6910
6970 6980 6990 7000 7010 7020 7030
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7330 7340 7350 7360 7370 7380 7390

7712448

Fig. 16

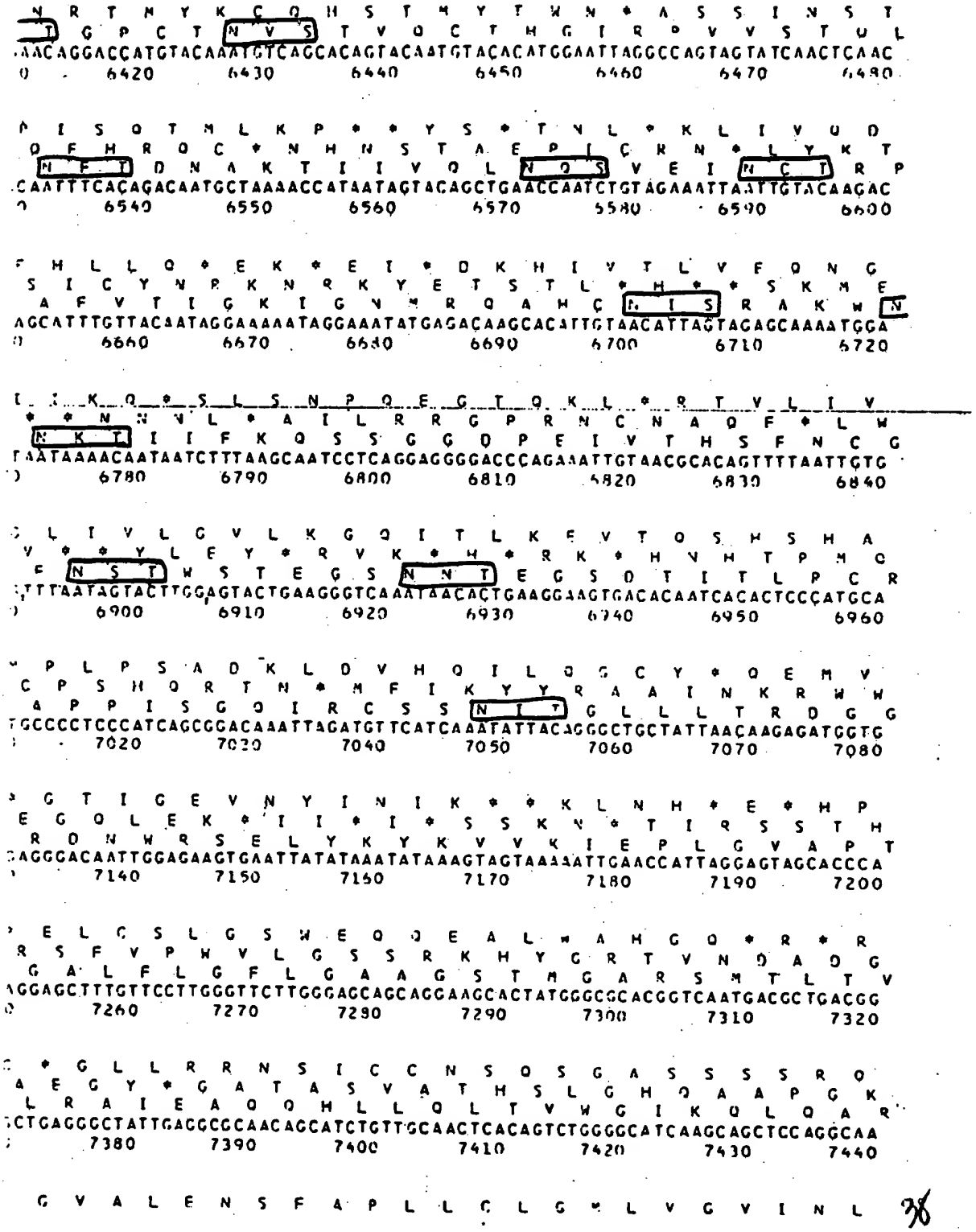
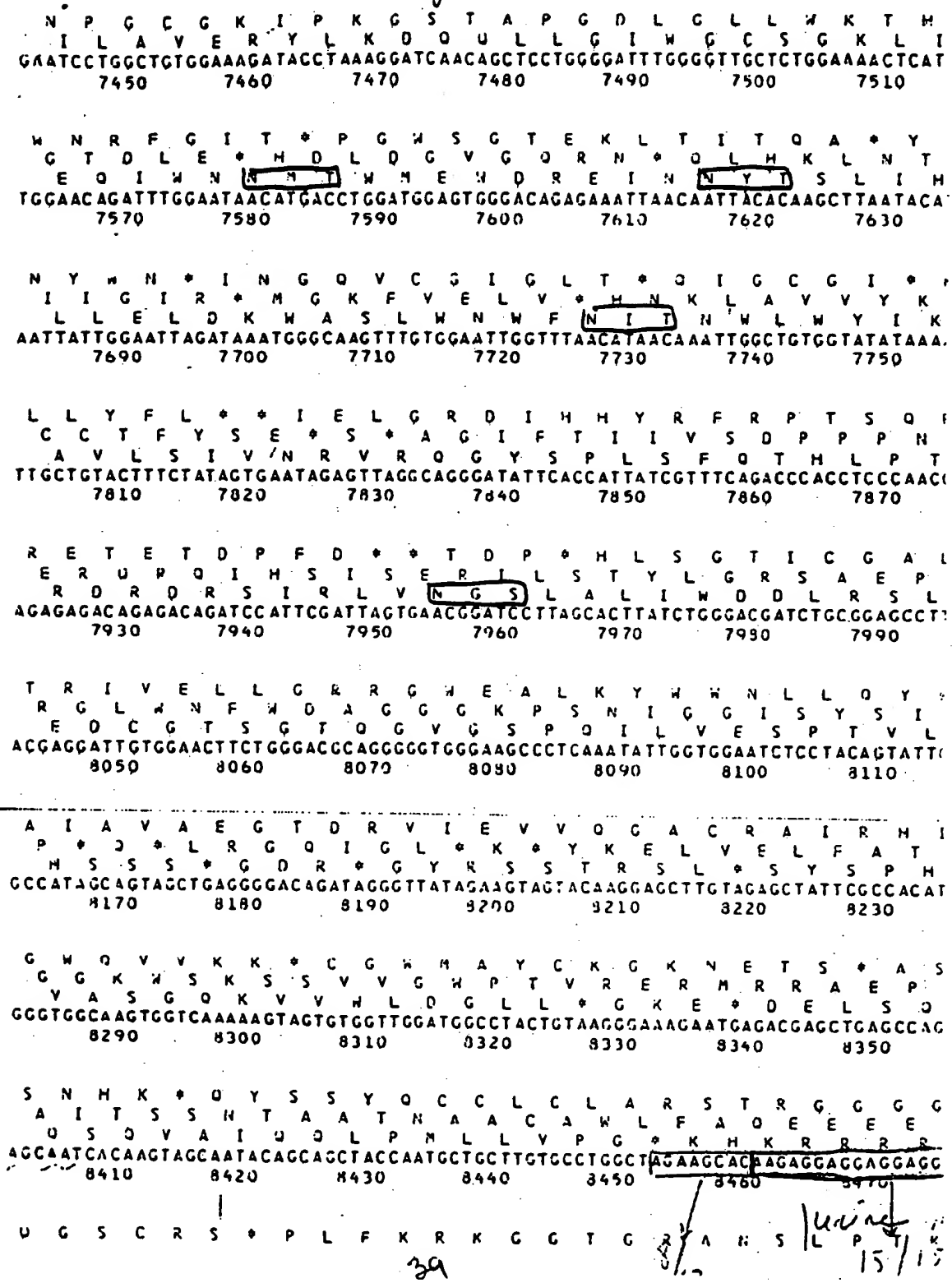


Fig 17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7930 7940 7950 7960 7970 7990 7990
8050 8060 8070 8080 8090 8100 8110
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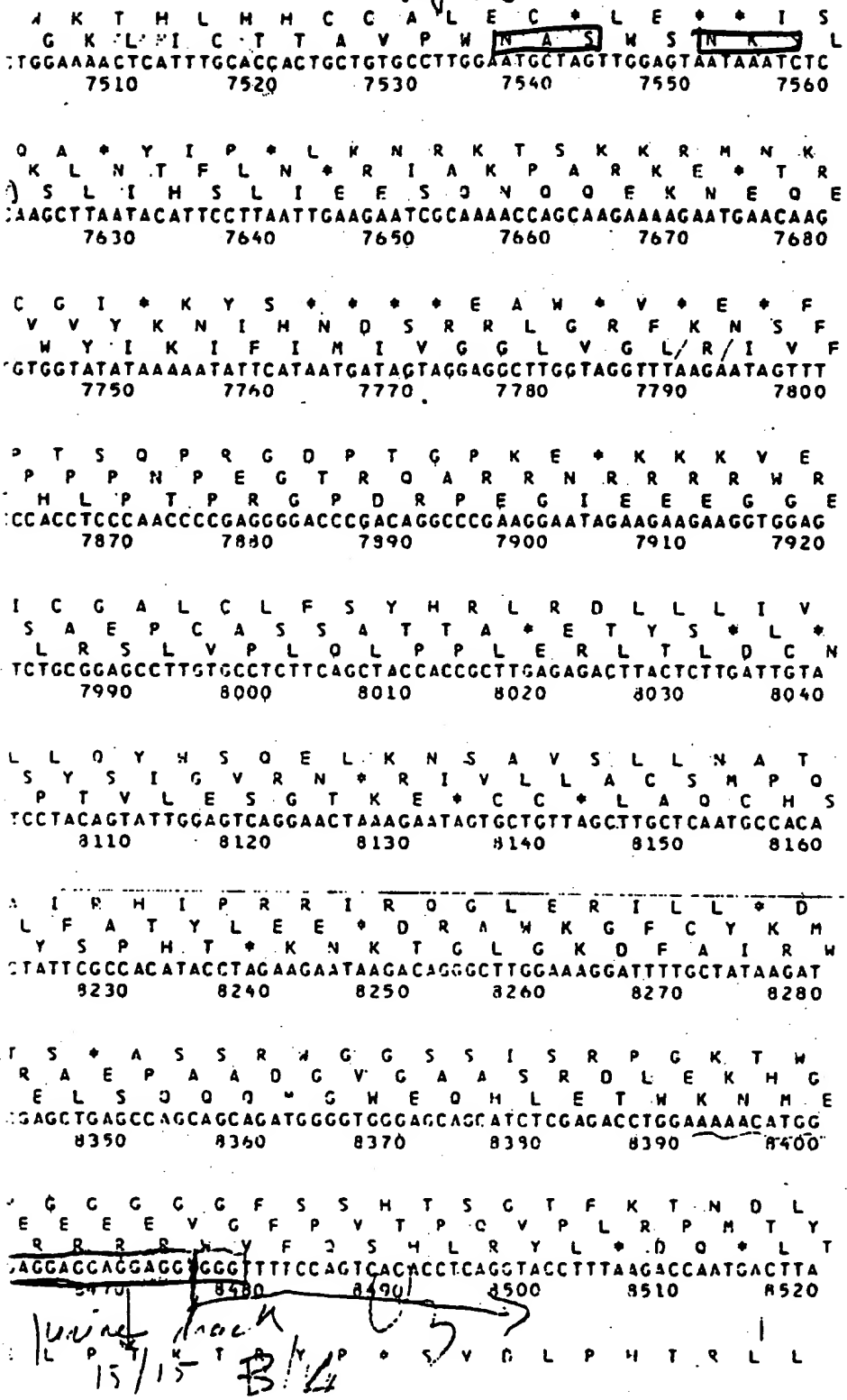
8410 8420 8430 8440 8450 8460

39

Fig 18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7750 7760 7770 7780 7790 7800
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7990 8000 8010 8020 8030 8040
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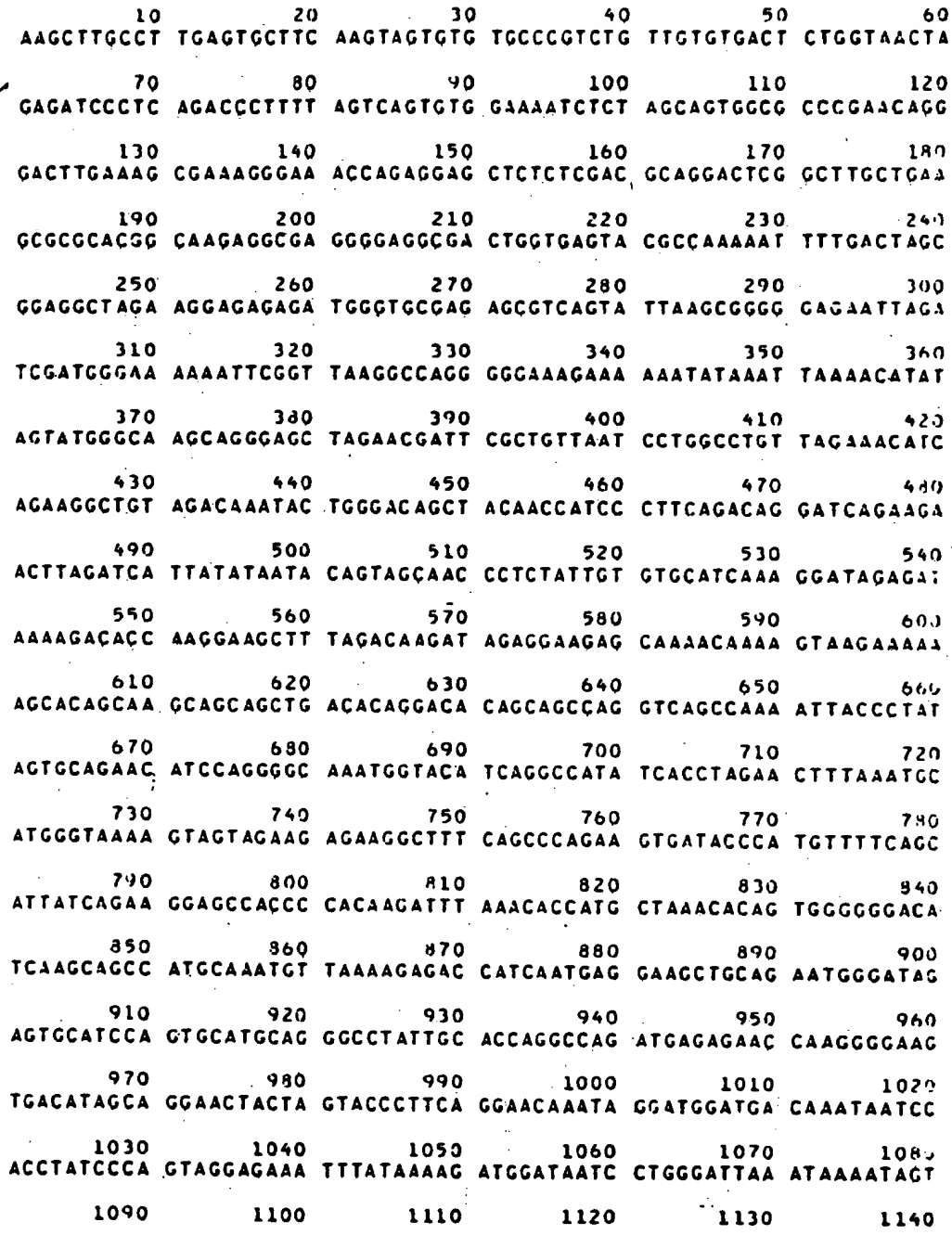
8230 8240 8250 8260 8270 8280
8350 8360 8370 8390 8390 8400
8500 8510 8520
15/15 B/L

Fig 19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130 140 150 160 170 180
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190 200 210 220 230 240
GCGCGCACGG CAAGAGGCGA GGGGAGGCGA CTGGTGAGTA CGCCAAAAAT TTTGACTAGC
250 260 270 280 290 300
GGAGGCTAGA AGGAGAGAGA TGGGTGCGAG AGCGTCAGTA TTAAGCGGGG GAGAATTAGA
310 320 330 340 350 360
TCGATGGGAA AAAATTCGGT TAAGGCCAGG GGGAAAGAAA AAATATAAAT TAAAACATAT
370 380 390 400 410 420
AGTATGGGCA AGCAGGGAGC TAGAACGATT CGCTGTTAAT CCTGGCCTGT TAGAAACATC
430 440 450 460 470 480
AGAAGGCTGT AGACAAATAC TGGGACAGCT ACAACCATCC CTTCAGACAG GATCAGAAGA
490 500 510 520 530 540
ACTTAGATCA TTATATAATA CAGTAGCAAC CCTCTATTGT GTGCATCAAA GGATAGAGAT
550 560 570 580 590 600
AAAAGACACC AAGGAAGCTT TAGACAAGAT AGAGGAAGAG CAAAACAAAA GTAAGAAAAA
610 620 630 640 650 660
AGCACAGCAA GCAGCAGCTG ACACAGGACA CAGCAGCCAG GTCAGCCAAA ATTACCCTAT
670 680 690 700 710 720
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730 740 750 760 770 780
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790 800 810 820 830 840
ATTATCAGAA GGAGCCACCC CACAAGATTT AAACACCATG CTAAACACAG TGGGGGGACA
850 860 870 880 890 900
TCAAGCAGCC ATGCAAATGT TAAAAGAGAC CATCAATGAG GAAGCTGCAG AATGGGATAG
910 920 930 940 950 960
AGTGCATCCA GTGCATGCAG GGCCTATTGC ACCAGGCCAG ATGAGAGAAC CAAGGGGAAG
970 980 990 1000 1010 1020
TGACATAGCA GGAACTACTA GTACCCTTCA GGAACAAATA GGATGGATGA CAAATAATCC
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ACCTATCCCA GTAGGAGAAA TTTATAAAAG ATGGATAATC CTGGGATTAA ATAAAATAGT
1090 1100 1110 1120 1130 1140

Fig 20

```
AAGAATGTAT AGCCCTACCA GCATTCTGGA CATAAGACAA GGACCAAAAG AACCCTTTAG

      1150        1160        1170        1180        1190        1200
AGACTATGTA GACCGGTTCT ATAAAACTCT AAGAGCCGAG CAAGCTTCAC AGGAGGTAAA

      1210        1220        1230        1240        1250        1260
AAATTGGATG ACAGAAACCT TGTTGGTCCA AAATGCGAAC CCAGATTGTA AGACTATTTT

      1270        1280        1290        1300        1310        1320
AAAAGCATTG GGACCAGCAG CTACACTAGA AGAAATGATG ACAGCATGTC AGGGAGTGGG

      1330        1340        1350        1360        1370        1380
AGGACCCGGC CATAAGGCAA GAGTTTTGGC TGAAGCAATG AGCCAAGTAA CAAATTCAGC

      1390        1400        1410        1420        1430        1440
TACCATAATC ATGCAAAGAG GCAATTTTAG GAACCAAAGA AAGATTGTTA AGTGTTTCAA

      1450        1460        1470        1480        1490        1500
TTGTGGCAAA GAAGGGCACA TAGCCAGAAA TTGCAGGGCC CCTAGGAAAA AGGGCTGTTG

      1510        1520        1530        1540        1550        1560
GAAATGTGGA AAGGAAGGAC ACCAAATGAA AGATTGTACT GAGAGACAGG CTAATTTTTT

      1570        1580        1590        1600        1610        1620
AGGGAAGATC TGGCCTTCCT ACAAGGGAAG GCCAGGGAAT TTTCTTCAGA GCAGACCAGA

      1630        1640        1650        1660        1670        1680
GCCAACAGCC CCACCAGAAG AGAGCTTCAG GTCTGGGGTA GAGACAACAA CTCCCTCTCA

      1690        1700        1710        1720        1730        1740
GAAGCAGGAG CCGATAGACA AGGAACTGTA TCCTTTAACT TCCCTCAGAT CACTCTTTGG

      1750        1760        1770        1780        1790        1800
CAACGACCCC TCGTCACAAT AAAGATAGGG GGGCAACTAA AGGAAGCTCT ATTAGATACA

      1810        1820        1830        1840        1850        1860
GGAGCAGATG ATACAGTATT AGAAGAAATG AGTTTGCCAG GAAGATGGAA ACCAAAAATG

      1870        1880        1890        1900        1910        1920
ATAGGGGGAA TTGGAGGTTT TATCAAAGTA AGACAGTATG ATCAGATACT CATAGAAATC

      1930        1940        1950        1960        1970        1980
TCTGGACATA AAGCTATAGG TACAGTATTA GTAGGACCTA CACCTGTCAA CATAATTGGA

      1990        2000        2010        2020        2030        2040
AGAAATCTGT TGACTCAGAT TGGTTGCACT TTAAATTTTC CCATTAGTCC TATTGAAACT

      2050        2060        2070        2080        2090        2100
GTACCAGTAA AATTAAAGCC AGGAATGGAT GGCCCAAAAG TTAAACAATG GCCATTGACA

      2110        2120        2130        2140        2150        2160
GAAGAAAAAA TAAAAGCATT AGTAGAAATT TGTACAGAAA TGGAAAAGGA AGGGAAAATT

      2170        2180        2190        2200        2210        2220
TCAAAAATTG GGCCTGAAAA TCCATACAAT ACTCCAGTAT TTGCCATAAA GAAAAAAGAC

      2230        2240        2250        2260        2270        2280
AGTACTAAAT GGAGAAAATT AGTAGATTTC AGAGAACTTA ATAAGAGAAC TCAAGACTTC

      2290        2300        2310        2320        2330        2340
TGGGAAGTTC AATTAGGAAT ACCACATCCC GCAGGGTTAA AAAAGAAAAA ATCAGTAACA

      2350        2360        2370        2380        2390        2400
```

42

Fig 9

GTGCTGGATG TGGGTGATGC ATATTTTTCA GTTCCCTTAG ATGAAGACTT CAGGAAGTAT

2410 2420 2430 2440 2450 2460
ACTGCATTTA CCATACCTAG TATAAACAAT GAGACACCAG GGATTAGATA TCAGTACAAT

2470 2480 2490 2500 2510 2520
GTGCTTCCAC AGGGATGGAA AGGATCACCA GCAATATTCC AAAGTAGCAT GACAAAAATC

2530 2540 2550 2560 2570 2580
TTAGAGCCTT TTAGAAAACA AAATCCAGAC ATAGTTATCT ATCAATACAT GGATGATTTG

2590 2600 2610 2620 2630 2640
TATGTAGGAT CTGACTTAGA AATAGGGCAG CATAGAACAA AAATAGAGGA GCTGAGACAA

2650 2660 2670 2680 2690 2700
CATCTGTTGA GGTGGGGACT TACCACACCA GACAAAAAAC ATCAGAAAGA ACCTCCATTC

2710 2720 2730 2740 2750 2760
CTTTGGATGG GTTATGAACT CCATCCTGAT AAATGGACAG TACAGCCTAT AGTGCTGCCA

2770 2780 2790 2800 2810 2820
GAAAAAGACA GCTGGACTGT CAATGACATA CAGAAGTTAG TGGGAAAATT GAATTGGGCA

2830 2840 2850 2860 2870 2880
AGTCAGATTT ACCCAGGGAT TAAAGTAAGG CAATTATGTA AACTCCTTAG AGGAACCAAA

2890 2900 2910 2920 2930 2940
GCACTAACAG AAGTAATACC ACTAACAGAA GAAGCAGAGC TAGAACTGGC AGAAAACAGA

2950 2960 2970 2980 2990 3000
GAGATTCTAA AAGAACCAGT ACATGGAGTG TATTATGACC CATCAAAAGA CTTAATAGCA

3010 3020 3030 3040 3050 3060
GAAATACAGA AGCAGGGGCA AGGCCAATGG ACATATCAAA TTTATCAAGA GCCATTTAAA

3070 3080 3090 3100 3110 3120
AATCTGAAAA CAGGAAAATA TGCAAGAACG AGGGGTGCCC ACACTAATGA TGTAAAACAA

3130 3140 3150 3160 3170 3180
TTAACAGAGG CAGTGCAAAA AATAACCACA GAAAGCATAG TAATATGGGG AAAGACTCCT

3190 3200 3210 3220 3230 3240
AAATTTAAAC TACCCATACA AAAGGAAACA TGGGAAACAT GGTGGACAGA GTATTGGCAA

3250 3260 3270 3280 3290 3300
GCCACCTGGA TTCCTGAGTG GGAGTTTGTC AATACCCCTC CTTTAGTGAA ATTATGCTAC

3310 3320 3330 3340 3350 3360
CAGTTAGAGA AAGAACCCAT AGTAGGAGCA GAAACGTTCT ATGTAGATGG GGCAGCTAGC

3370 3380 3390 3400 3410 3420
AGGGAGACTA AATTAGGAAA AGCAGGATAT GTTACTAATA GAGGAAGACA AAAAGTTGTC

3430 3440 3450 3460 3470 3480
ACCCTAACTG ACACAACAAA TCAGAAGACT GAGTTACAAG CAATTCATCT AGCTTTGCAG

3490 3500 3510 3520 3530 3540
GATTCGGGAT TAGAAGTAAA TATAGTAACA GACTCACAAT ATGCATTAGG AATCATTCAA

3550 3560 3570 3580 3590 3600
GCACAACCAG ATAAAAGTGA ATCAGAGTTA GTCAATCAAA TAATAGAGCA GTTAATAAAA

43 3610 3620 3630 3640 3650 3660

Fig 22

AAG.AAAA.. TCTATCTGGC ATGGGTACCA GCACACAAAG GAATTGGAGG AAATGAACAA

3670 3680 3690 3700 3710 3720
GTAGATAAAT TAGTCAGTGC TGGAATCAGG AAAGTACTAT TTTTAGATGG AATAGATAAG

3730 3740 3750 3760 3770 3780
GCCCAAGATG AACATGAGAA ATATCACAGT AATTGGAGAG CAATGGCTAG TGATTTTAAC

3790 3800 3810 3820 3830 3840
CTGCCACCTG TAGTAGCAAA AGAAATAGTA GCCAGCTGTG ATAAATGTCA GCTAAAAGGA

3850 3860 3870 3880 3890 3900
GAAGCCATGC ATGGACAAGT AGACTGTAGT CCAGGAATAT GGCAACTAGA TTGTACACAT

3910 3920 3930 3940 3950 3960
TTAGAAGGAA AAGTTATCCT GGTAGCAGTT CATGTAGCCA GTGGATATAT AGAAGCAGAA

3970 3980 3990 4000 4010 4020
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4030 4040 4050 4060 4070 4080
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4090 4100 4110 4120 4130 4140
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4150 4160 4170 4180 4190 4200
CAAGGAGTAG TAGAATCTAT GAATAAAGAA TTAAAGAAAA TTATAGGCCA GGTAAGAGAT

4210 4220 4230 4240 4250 4260
CAGGCTGAAC ATCTTAAGAC AGCAGTACAA ATGGCAGTAT TCATCCACAA TTTTAAAAGA

4270 4280 4290 4300 4310 4320
AAAGGGGGGA TTGGGGGGTA CAGTGCAGGG GAAAGAATAG TAGACATAAT AGCAACAGAC

4330 4340 4350 4360 4370 4380
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4390 4400 4410 4420 4430 4440
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4450 4460 4470 4480 4490 4500
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4510 4520 4530 4540 4550 4560
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4570 4580 4590 4600 4610 4620
GATTAGAACA TGGAAAAGTT TAGTAAAACA CCATATGTAT GTTTCAGGGA AAGCTAGGGG

4630 4640 4650 4660 4670 4680
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4690 4700 4710 4720 4730 4740
CCCACTAGGG GATGCTAGAT TGGTAATAAC AACATATTGG GGTCTGCATA CAGGAGAAAG

4750 4760 4770 4780 4790 4800
AGACTGGCAT CTGGGTCAGG GAGTCTCCAT AGAATGGAGG AAAAAGAGAT ATAGCACACA

4810 4820 4830 4840 4850 4860
AGTAGACCCT GAACTAGCAG ACCAACTAAT TCATCTGTAT TACTTTGACT GTTTTTCAGA

44 4870 4880 4890 4900 4910 4920

Fig 23

CTCTGCTATA AGAAAGCCCT TATTAGGACA TATAGTTAGC CCTAGGTGTG AATATCAAGC

4930 4940 4950 4960 4970 4980
AGGACATAAC AAGGTAGGAT CTCTACAATA CTTGGCACTA GCAGCATTAA TAACACCAAA

4990 5000 5010 5020 5030 5040
AAAGATAAAG CCACCTTTGC CTAGTGTTAC GAAACTGACA GAGGATAGAT GGAACAAGCC

5050 5060 5070 5080 5090 5100
CCAGAAGACC AAGGGCCACA GAGGGAGCCA CACAATGAAT GGACACTAGA GCTTTTAGAG

5110 5120 5130 5140 5150 5160
GAGCTTAAGA ATGAAGCTGT TAGACATTTT CCTAGGATTT GGCTCCATGG CTTAGGGCAA

5170 5180 5190 5200 5210 5220
CATATCTATG AAACTTATGG GGATACTTGG GCAGGAGTGG AAGCCATAAT AAGAATTCTG

5230 5240 5250 5260 5270 5280
CAACAACTGC TGTTTATCCA TTTCAGAATT GGGTGTCGAC ATAGCAGAAT AGGCGTTACT

5290 5300 5310 5320 5330 5340
CAACAGAGGA GAGCAAGAAA TGGAGCCAGT AGATCCTAGA CTAGAGCCCT GGAAGCATCC

5350 5360 5370 5380 5390 5400
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5410 5420 5430 5440 5450 5460
CCAAGTTTGT TTCACAACAA AAGCCTTAGG CATCTCCTAT GGCAGGAAGA AGCGGAGACA

5470 5480 5490 5500 5510 5520
GCGACGAAGA CCTCCTCAAG GCAGTCAGAC TCATCAAGTT TCTCTATCAA AGCAGTAAGT

5530 5540 5550 5560 5570 5580
AGTACATGTA ATGCAACCTA TACAAATAGC AATAGCAGCA TTAGTAGTAG CAATAATAAT

5590 5600 5610 5620 5630 5640
AGCAATAGTT GTGTGGTCCA TAGTAATCAT AGAATATAGG AAAATATTAA GACAAAGAAA

5650 5660 5670 5680 5690 5700
AATAGACAGG TTAATTGATA GACTAATAGA AAGAGCAGAA GACAGTGGCA ATGAGAGTGA

5710 5720 5730 5740 5750 5760
AGGAGAAATA TCAGCACTTG TGGAGATGGG GGTGGAAATG GGGCACCATG CTCCTTGGGA

5770 5780 5790 5800 5810 5820
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5830 5840 5850 5860 5870 5880
TGTGGAAGGA AGCAACCACC ACTCTATTTT GTGCATCAGA TGCTAAAGCA TATGATACAG

5890 5900 5910 5920 5930 5940
AGGTACATAA TGTTTGGGCC ACACATGCCT GTGTACCCAC AGACCCCAAC CCACAAGAAG

5950 5960 5970 5980 5990 6000
TAGTATTGGT AAATGTGACA GAAAATTTTA ACATGTGGAA AAATGACATG GTAGAACAGA

6010 6020 6030 6040 6050 6060
TGCATGAGGA TATAATCAGT TTATGGGATC AAAGCCTAAA GCCATGTGTA AAATTAACCC

6070 6080 6090 6100 6110 6120
CACTCTGTGT TAGTTTAAAG TGCACTGATT TGGGGAATGC TACTAATACC AATAGTAGTA

6130 6140 6150 6160 6170 6180

45

ATACCAATAG TAGTAGCGGG GAAATGATGA TGGAGAAAGG AGAGATAAAA AACTGCTCTT

6190 6200 6210 6220 6230 6240
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6250 6260 6270 6280 6290 6300
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6310 6320 6330 6340 6350 6360
CAGTCATTAC ACAGGCCTGT CCAAAGGTAT CCTTTGAGCC AATTCCCATA CATTATTGTG

6370 6380 6390 6400 6410 6420
CCCCGGCTGG TTTTGCGATT CTAAAATGTA ATAATAAGAC GTTCAATGGA ACAGGACCAT

7924

6430 6440 6450 6460 6470 6480
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6490 6500 6510 6520 6530 6540
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6550 6560 6570 6580 6590 6600
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6610 6620 6630 6640 6650 6660
CCAACAACAA TACAAGAAAA AGTATCCGTA TCCAGAGGGG ACCAGGGAGA GCATTTGTTA

6670 6680 6690 6700 6710 6720
CAATAGGAAA AATAGGAAAT ATGAGACAAG CACATTGTAA CATTAGTAGA GCAAAATGGA

6730 6740 6750 6760 6770 6780
ATGCCACTTT AAAACAGATA GCTAGCAAAT TAAGAGAACA ATTTGGAAAT AATAAAACAA

6790 6800 6810 6820 6830 6840
TAATCTTTAA GCAATCCTCA GGAGGGGACC CAGAAATTGT AACGCACAGT TTTAATTGTG

6850 6860 6870 6880 6890 6900
GAGGGGAATT TTTCTACTGT AATTCAACAC AACTGTTTAA TAGTACTTGG TTTAATAGTA

6910 6920 6930 6940 6950 6960
CTTGGAGTAC TGAAGGGTCA AATAACACTG AAGGAAGTGA CACAATCACA CTCCCATGCA

6970 6980 6990 7000 7010 7020
GAATAAAACA ATTTATAAAC ATGTGGCAGG AAGTAGGAAA AGCAATGTAT GCCCCTCCCA

7030 7040 7050 7060 7070 7080
TCAGCGGACA AATTAGATGT TCATCAAATA TTACAGGGCT GCTATTAACA AGAGATGGTG

7090 7100 7110 7120 7130 7140
GTAATAACAA CAATGGGTCC GAGATCTTCA GACCTGGAGG AGGAGATATG AGGGACAATT

7150 7160 7170 7180 7190 7200
GGAGAAGTGA ATTATATAAA TATAAAGTAG TAAAAATTGA ACCATTAGGA GTAGCACCCA

7210 7220 7230 7240 7250 7260
CCAAGGCAAA GAGAAGAGTG GTGCAGAGAG AAAAAAGAGC AGTGGGAATA GGAGCTTTGT

7270 7280 7290 7300 7310 7320
TCCTTGGGTT CTTGGGAGCA GCAGGAAGCA CTATGGGCGC ACGGTCAATG ACGCTGACGG

7330 7340 7350 7360 7370 7380
TACAGGCCAG ACAATTATTG TCTGGTATAG TGCAGCAGCA GAACAATTTG CTGAGGGCTA

46 7390 7400 7410 7420 7430 7440

TTGAGGCGCA ACAGCATCTG TTGCAACTCA CAGTCTGGGG CATCAAGCAG CTCCAGGCAA

7450 7460 7470 7480 7490 7500
GAATCCTGGC TGTGGAAAGA TACCTAAAGG ATCAACAGCT CCTGGGGATT TGGGGTTGCT

7510 7520 7530 7540 7550 7560
CTGGAAAACT CATTTGCACC ACTGCTGTGC CTTGGAATGC TAGTTGGAGT AATAAATCTC

7570 7580 7590 7600 7610 7620
TGGAACAGAT TTGGAATAAC ATGACCTGGA TGCAGTGGGA CAGAGAAATT AACAATTACA

7630 7640 7650 7660 7670 7680
CAAGCTTAAT ACATTCCTTA ATTGAAGAAT CGCAAAACCA GCAAGAAAAG AATGAACAAG

7690 7700 7710 7720 7730 7740
AATTATTGGA ATTAGATAAA TGGGCAAGTT TGTGGAATTG GTTTAACATA ACAAATTGGC

7750 7760 7770 7780 7790 7800
TGTGGTATAT AAAAATATTC ATAATGATAG TAGGAGGCTT GGTAGGTTTA AGAATAGTTT

7810 7820 7830 7840 7850 7860
TTGCTGTACT TTCTATAGTG AATAGAGTTA GGCAGGGATA TTCACCATTA TCGTTTCAGA

7870 7880 7890 7900 7910 7920
CCCACCTCCC AACCCCGAGG GGACCCGACA GGCCCGAAGG AATAGAAGAA GAAGGTGGAG

7930 7940 7950 7960 7970 7980
AGAGAGACAG AGACAGATCC ATTCGATTAG TGAACGGATC CTTAGCACTT ATCTGGGACG

7990 8000 8010 8020 8030 8040
ATCTGCGGAG CCTTGTGCCT CTTCAGCTAC CACCGCTTGA GAGACTTACT CTTGATTGTA

8050 8060 8070 8080 8090 8100
ACGAGGATTG TGGAACTTCT GGGACGCAGG GGGTGGGAAG CCCTCAAATA TTGGTGGAAT

8110 8120 8130 8140 8150 8160
CTCCTACAGT ATTGGAGTCA GGAACTAAAG AATAGTGCTG TTAGCTTGCT CAATGCCACA

8170 8180 8190 8200 8210 8220
GCCATAGCAG TAGCTGAGGG GACAGATAGG GTTATAGAAG TAGTACAAGG AGCTTGTAGA

8230 8240 8250 8260 8270 8280
GCTATTCGCC ACATACCTAG AAGAATAAGA CAGGGCTTGG AAAGGATTTT GCTATAAGAT

8290 8300 8310 8320 8330 8340
GGGTGGCAAG TGGTCAAAAA GTAGTGTGGT TGGATGGCCT ACTGTAAGGG AAAGAATGAG

8350 8360 8370 8380 8390 8400
ACGAGCTGAG CCAGCAGCAG ATGGGGTGGG AGCAGCATCT CGAGACCTGG AAAAACATGG

8410 8420 8430 8440 8450 8460
AGCAATCACA AGTAGCAATA CAGCAGCTAC CAATGCTGCT TGTGCCTGGC TAGAAGCACA

8470 8480 8490 8500 8510 8520
AGAGGAGGAG GAGGTGGGTT TTCCAGTCAC ACCTCAGGTA CCTTTAAGAC CAATGACTTA

8530 8540 8550 8560 8570 8580
CAAGGCAGCT GTAGATCTTA GCCACTTTTT AAAAGAAAAG GGGGGACTGG AAGGGCTAAT

8590 8600 8610 8620 8630 8640
TCACTCCCAA CGAAGACAAG ATATCCTTGA TCTGTGGATC TACCACACAC AAGGCTACTT

8650 8660 8670 8680 8690 8700

CCCTGATTGG CAGAACTACA CACCAGGGCC AGGGGTCAGA TATCCACTGA CCTTTGGATG

8710	8720	8730	8740	8750	8760
GTGCTACAAG	CTAGTACCAG	TTGAGCCAGA	TAAGGTAGAA	GAGGCCAATA	AAGGAGAGAA
8770	8780	8790	8800	8810	8820
CACCAGCTTG	TTACACCCTG	TGAGCCTGCA	TGGAATGGAT	GACCCTGAGA	GAGAAGTGTT
8830	8840	8850	8860	8870	8880
AGAGTGGAGG	TTTGACAGCC	GCCTAGCATT	TCATCACGTG	GCCCGAGAGC	TGCATCCGGA
8890	8900	8910	8920	8930	8940
GTACTTCAAG	AACTGCTGAC	ATCGAGCTTG	CTACAAGGGA	CTTTCCGCTG	GGGACTTTCC
8950	8960	8970	8980	8990	9000
AGGGAGGCGT	GGCCTGGGCG	GAACTGGGGA	GTGGCGAGCC	CTCAGATGCT	GCATATAAGC
9010	9020	9030	9040	9050	9060
AGCTGCTTTT	TGCCTGTACT	GGGTCTCTCT	GGTTAGACCA	GATTTGAGCC	TGGGAGCTCT
9070	9080	9090	9100	0	0
CTGGCTAACT	AGGGAACCCA	CTGCTTAAGC	CTCAATAAAG	CTT	

Fig 9b